Access DB# 120873

SEARCH REQUEST FORM

Scientific and Technical Information Center

Requester's Full Name: ANDREA RAGONESE Examiner # : 77465 Date: 4/30/2004
Art Unit: 3743 Phone Number 30 6 - 4055 Serial Number: 10/613358
Mail Box and Bldg/Room Location: PK 1 - 11-E-50 Results Format Preferred (circle): PAPER DISK E-MAIL

If more than one search is submitted, please prioritize searches in order of need.

****

Please provide a detailed statement of the search topic, and describe as specifically as possible the subject matter to be searched. Include the elected species or structures, keywords, synonyms, acronyms, and registry numbers, and combine with the concept or utility of the invention. Define any terms that may have a special meaning. Give examples or relevant citations, authors, etc, if known. Please attach a copy of the cover sheet, pertinent claims, and abstract.

Title of Invention: LONG TERM OXYGEN THERAPY SYSTEM

Inventors (please provide full names): DON TANAKA

Earliest Priority Filing Date: 7/3/2003

***For Sequence Searches Only* Please include all pertinent information (parent, child, divisional, or issued patent numbers) along with the appropriate serial number.**

See attached

= PG PUB

2004/0024356

****

STAFF USE ONLY Type of Search Vendors and cost where applicable

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Set      Items   Description
S1         277   AU=(TANAKA D? OR TANAKA, D?)
S2        2913   OXYGEN(2N)THERAP? OR COPD OR CHRONIC()OBSTRUCT?()(LUNG? OR
                 PULMON?)
S3       94384   IC=A61M?
S4          11   S1 AND S2:S3
S5          11   IDPAT (sorted in duplicate/non-duplicate order)
? show files
File 347:JAPIO Nov 1976-2003/Dec(Updated 040402)
         (c) 2004 JPO & JAPIO
File 350:Derwent WPIX 1963-2004/UD,UM &UP=200427
         (c) 2004  Thomson Derwent
?
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AUTHOR - INVENTOR SEARCH

PAT LIT / NON PAT LIT

FULLTEXT / BIBLIOG FILES

10/613860 APPLICATION

5/3,K/1 (Item 1 from file: 350)
DIALOG(R)File 350:Derwent WPIX
(c) 2004 Thomson Derwent. All rts. reserv.

016046817
WPI Acc No: 2004-204668/200420
XRAM Acc No: C04-080914
XRPX Acc No: N04-162613
Collateral ventilation bypass trap system for removing trapped air in emphysematous lungs, comprises at least one conduit having first end connected to containment vessel and second end passing through thoracic wall and lung of patient
Patent Assignee: CORDIS CORP (CRDC); TANAKA D (TANA-I)
Inventor: **TANAKA D**
Number of Countries: 033 Number of Patents: 003
Patent Family:

Patent No	Kind	Date	Applicat No	Kind	Date	Week
EP 1393760	A1	20040303	EP 2003255306	A	20030827	200420 B
US 20040040555	A1	20040304	US 2002406624	P	20020828	200420
			US 2003613860	A	20030703	
CA 2438823	A1	20040228	CA 2438823	A	20030828	200421

Priority Applications (No Type Date): US 2003613860 A 20030703; US 2002406624 P 20020828
Patent Details:

Patent No	Kind	Lan	Pg	Main IPC	Filing Notes
EP 1393760	A1	E	16	A61M-001/00	

Designated States (Regional): AL AT BE BG CH CY CZ DE DK EE ES FI FR GB GR HU IE IT LI LT LU LV MC MK NL PT RO SE SI SK TR

US 20040040555 A1 A61M-016/00 Provisional application US 2002406624

CA 2438823 A1 E A61M-016/00
Inventor: **TANAKA D**

Abstract (Basic):
... system is used for removing trapped air in emphysematous lungs, for treating hypoxia caused by **chronic obstructive** pulmonary disease such as emphysema and chronic bronchitis...

...The system increases the expiratory flow from an individual suffering from **chronic obstructive pulmonary** disease...
International Patent Class (Main): **A61M-001/00** ...

... **A61M-016/00**
International Patent Class (Additional): **A61M-016/10** ...

... **A61M-016/20**

5/3,K/2 (Item 2 from file: 350)
DIALOG(R)File 350:Derwent WPIX
(c) 2004 Thomson Derwent. All rts. reserv.

016000773 **Image available**
WPI Acc No: 2004-158623/200416
XRAM Acc No: C04-063267
XRPX Acc No: N04-126751
Long-term oxygen therapy **system for treating hypoxemic patients having** chronic obstructive pulmonary **disease, includes oxygen supply, valve, conduit, and sealing device that provides fluid tight seal**

10/613358
Applicant

between conduit and thoracic wall
Patent Assignee: CORDIS CORP (CRDC); TANAKA D (TANA-I)
Inventor: **TANAKA D**
Number of Countries: 033 Number of Patents: 003
Patent Family:

Patent No	Kind	Date	Applicat No	Kind	Date	Week
EP 1386635	A1	20040204	EP 2003254748	A	20030729	200416 B
CA 2436483	A1	20040131	CA 2436483	A	20030731	200416
US 20040024356	A1	20040205	US 2002399907	P	20020731	200416
			US 2003613358	A	20030703	

Priority Applications (No Type Date): US 2003613358 A 20030703; US 2002399907 P 20020731
Patent Details:

Patent No	Kind	Lan	Pg	Main IPC	Filing Notes
EP 1386635	A1	E	13	A61M-037/00	
CA 2436483	A1	E		A61M-016/00	
US 20040024356	A1			A61M-029/00	Provisional application US 2002399907

Designated States (Regional): AL AT BE BG CH CY CZ DE DK EE ES FI FR GB GR HU IE IT LI LT LU LV MC MK NL PT RO SE SI SK TR

Long-term oxygen therapy **system for treating hypoxemic patients having** chronic obstructive pulmonary **disease, includes oxygen supply, valve, conduit**, and sealing device that provides fluid tight seal **between**...
Inventor: **TANAKA D**

Abstract (Basic):
... A long-term **oxygen therapy** system (100) has an oxygen supply (102); valve (106); conduit(s) (104) having a first...
... For the treatment of hypoxemic patients having **chronic obstructive pulmonary** disease (claimed), e.g. emphysema or chronic bronchitis...

...The inventive long-term **oxygen therapy** system improves **oxygen** transfer efficiency in the lungs to reduce oxygen supply requirements, which in turn reduces the...

...The figure is a diagrammatic view of a long term **oxygen therapy** system of the invention...

...Long term **oxygen therapy** system (100...
International Patent Class (Main): **A61M-016/00** ...

... **A61M-029/00** ...

... **A61M-037/00**
International Patent Class (Additional): **A61M-031/00**

5/3,K/3 (Item 3 from file: 350)
DIALOG(R)File 350:Derwent WPIX

015572879 **Image available**
WPI Acc No: 2003-635036/200360
Related WPI Acc No: 2001-183025; 2002-665488; 2002-731244; 2003-090179; 2003-090394; 2003-256991; 2003-877133; 2004-059032; 2004-081957; 2004-118964
XRAM Acc No: C03-173497
XRPX Acc No: N03-505055

Gaseous flow altering conduit for chronic obstructive pulmonary **disease treatment, has cage structure having opening and cage passage way in fluid communication with passageway of center section**

Patent Assignee: BIGGS M (BIGG-I); CHANDOS D (CHAN-I); COLLINSON M (COLL-I) ; COOPER J D (COOP-I); KAPLAN G (KAPL-I); KARABEY H (KARA-I); KEAST T (KEAS-I); LOOMAS B (LOOM-I); REDMOND R (REDM-I); ROSCHAK E (ROSC-I); SAENZ S (SAEN-I); TANAKA D (TANA-I); THOMPSON D (THOM-I); VIDAL C (VIDA-I)

Inventor: BIGGS M; CHANDOS D; COLLINSON M; COOPER J D; KAPLAN G; KARABEY H; KEAST T; LOOMAS B; REDMOND R; ROSCHAK E; SAENZ S; **TANAKA D** ; THOMPSON D; VIDAL C

Number of Countries: 001 Number of Patents: 001

Patent Family:

Patent No	Kind	Date	Applicat No	Kind	Date	Week
US 20030070676	A1	20030417	US 99147528	P	19990805	200360 B
			US 2000176141	P	20000114	
			US 2000633651	A	20000807	
			US 2001269130	P	20010214	
			US 2001317338	P	20010904	
			US 2001947144	A	20010904	
			US 2001334642	P	20011129	
			US 2002367436	P	20020320	
			US 2002374022	P	20020419	
			US 2002387163	P	20020607	
			US 2002235240	A	20020904	

Priority Applications (No Type Date): US 2002235240 A 20020904; US 99147528 P 19990805; US 2000176141 P 20000114; US 2000633651 A 20000807; US 2001269130 P 20010214; US 2001317338 P 20010904; US 2001947144 A 20010904 ; US 2001334642 P 20011129; US 2002367436 P 20020320; US 2002374022 P 20020419; US 2002387163 P 20020607

Patent Details:

Patent No	Kind	Lan	Pg	Main IPC	Filing Notes
US 20030070676	A1		62	A61M-016/00	Provisional application US 99147528
					Provisional application US 2000176141
					CIP of application US 2000633651
					Provisional application US 2001269130
					Provisional application US 2001317338
					CIP of application US 2001947144
					Provisional application US 2001334642
					Provisional application US 2002367436
					Provisional application US 2002374022
					Provisional application US 2002387163

Gaseous flow altering conduit for chronic obstructive pulmonary **disease treatment, has cage structure having opening and cage passage way in fluid communication with...**

...Inventor: **TANAKA D**

Abstract (Basic):

... For altering gaseous flow within lung to improve expiration cycle of individual having **chronic obstructive pulmonary** disease including chronic bronchitis, emphysema and some types of asthma. Also used for delivering drugs...

International Patent Class (Main): **A61M-016/00**

5/3,K/4 (Item 4 from file: 350)

DIALOG(R)File 350:Derwent WPIX

015196455 **Image available**
WPI Acc No: 2003-256991/200325
Related WPI Acc No: 2001-183025; 2002-665488; 2002-731244; 2003-090179; 2003-090394; 2003-635036; 2003-877133; 2004-059032; 2004-081957; 2004-118964
XRPX Acc No: N03-203827

Conduit for altering gaseous flow in lung of chronic obstructive pulmonary **disease victim has cage structure adjacent conduit second end with opening and cage passageway in fluid communication with center section passageway**

Patent Assignee: BRONCUS TECHNOLOGIES INC (BRON-N)
Inventor: COLE C; ESTRIDGE T; KAPLAN G; LAUFER M D; LOOMAS B; REICH C J; ROSCHAK E; BIGGS M; CHANDOS D; COLLINSON M; COOPER J D; KARABEY H; KEAST T; REDMOND R; SAENZ S; **TANAKA D** ; THOMPSON D; VIDAL C
Number of Countries: 100 Number of Patents: 002
Patent Family:

Patent No	Kind	Date	Applicat No	Kind	Date	Week
WO 200320338	A2	20030313	WO 2002US28237	A	20020904	200325 B
US 20040073155	A1	20040415	US 2000176141	P	20000114	200426
			US 2000633651	A	20000807	
			US 2001908177	A	20010718	
			US 2001947144	A	20010904	
			US 2002387163	P	20020607	
			US 2002235240	A	20020904	
			US 2002420440	P	20021021	
			US 2003458085	A	20030609	

Priority Applications (No Type Date): US 2002387163 P 20020607; US 2001317338 P 20010904; US 2001947144 A 20010904; US 2001334642 P 20011129 ; US 2002367436 P 20020320; US 2002374022 P 20020419; US 2000176141 P 20000114; US 2000633651 A 20000807; US 2001908177 A 20010718; US 2002235240 A 20020904; US 2002420440 P 20021021; US 2003458085 A 20030609
Patent Details:

Patent No	Kind	Lan	Pg	Main IPC	Filing Notes
WO 200320338	A2	E	99	A61M-000/00	

Designated States (National): AE AG AL AM AT AU AZ BA BB BG BR BY BZ CA CH CN CO CR CU CZ DE DK DM DZ EC EE ES FI GB GD GE GH GM HR HU ID IL IN IS JP KE KG KP KR KZ LC LK LR LS LT LU LV MA MD MG MK MN MW MX MZ NO NZ OM PH PL PT RO RU SD SE SG SI SK SL TJ TM TN TR TT TZ UA UG US UZ VN YU ZA ZM ZW
Designated States (Regional): AT BE BG CH CY CZ DE DK EA EE ES FI FR GB GH GM GR IE IT KE LS LU MC MW MZ NL OA PT SD SE SK SL SZ TR TZ UG ZM ZW

US 20040073155	A1	A61F-002/04	Provisional application US 2000176141 Cont of application US 2000633651 CIP of application US 2001908177 CIP of application US 2001947144 Provisional application US 2002387163 CIP of application US 2002235240 Provisional application US 2002420440 Cont of patent US 6692494

Conduit for altering gaseous flow in lung of chronic obstructive pulmonary **disease victim has cage structure adjacent conduit second end with opening and cage passageway in...**
...Inventor: **TANAKA D**

Abstract (Basic):
... For **chronic obstructive pulmonary** disease victims...
...International Patent Class (Main): **A61M-000/00**

5/3,K/5 (Item 5 from file: 350)
DIALOG(R)File 350:Derwent WPIX
(c) 2004 Thomson Derwent. All rts. reserv.

015029662 **Image available**
WPI Acc No: 2003-090179/200308
Related WPI Acc No: 2001-183025; 2002-665488; 2002-731244; 2003-248441; 2003-256991; 2003-635036; 2003-877133; 2004-081957; 2004-118964
XRAM Acc No: C03-022787
XRPX Acc No: N03-071185

Placing of conduit within lung tissue for treating patient having chronic obstructive pulmonary **disease, by feeding guide wire to site within lung, advancing conduit using guide wire and placing within lung tissue**

Patent Assignee: BRONCUS TECHNOLOGIES INC (BRON-N)
Inventor: COOPER J D; DAVENPORT J M; KAPLAN G; LOOMAS B; **TANAKA D**
Number of Countries: 100 Number of Patents: 003
Patent Family:

Patent No	Kind	Date	Applicat No	Kind	Date	Week
US 20020111620	A1	20020815	US 2001269130	P	20010214	200308 B
			US 2001947144	A	20010904	
WO 200264190	A2	20020822	WO 2002US4610	A	20020214	200308
AU 2002248443	A1	20020828	AU 2002248443	A	20020214	200427

Priority Applications (No Type Date): US 2001269130 P 20010214; US 2001947144 A 20010904
Patent Details:

Patent No	Kind	Lan	Pg	Main IPC	Filing Notes
US 20020111620	A1		57	A61B-018/18	Provisional application US 2001269130
WO 200264190	A2	E		A61M-000/00	

Designated States (National): AE AG AL AM AT AU AZ BA BB BG BR BY BZ CA CH CN CO CR CU CZ DE DK DM DZ EC EE ES FI GB GD GE GH GM HR HU ID IL IN IS JP KE KG KP KR KZ LC LK LR LS LT LU LV MA MD MG MK MN MW MX MZ NO NZ OM PH PL PT RO RU SD SE SG SI SK SL TJ TM TN TR TT TZ UA UG US UZ VN YU ZA ZM ZW
Designated States (Regional): AT BE CH CY DE DK EA ES FI FR GB GH GM GR IE IT KE LS LU MC MW MZ NL OA PT SD SE SL SZ TR TZ UG ZM ZW

AU 2002248443	A1		A61M-000/00	Based on patent WO 200264190

Placing of conduit within lung tissue for treating patient having chronic obstructive pulmonary **disease, by feeding guide wire to site within lung, advancing conduit using guide wire and...**
...Inventor: **TANAKA D**

Abstract (Basic):
... for altering gaseous flow within a lung to improve the expiration cycle of patient having **chronic obstructive pulmonary** disease...
...International Patent Class (Main): **A61M-000/00**

5/3,K/6 (Item 6 from file: 350)
DIALOG(R)File 350:Derwent WPIX
(c) 2004 Thomson Derwent. All rts. reserv.

014910538 **Image available**
WPI Acc No: 2002-731244/200279

Related WPI Acc No: 2001-183025; 2002-665488; 2003-090179; 2003-090394; 2003-248441; 2003-256991; 2003-635036; 2003-877133; 2004-059032; 2004-081957; 2004-118964
XRPX Acc No: N02-576436
Tissue motion detection device for treatment of chronic obstructive pulmonary **disease, has transducer assembly with lens located at distal end of assembly, and heating element located away from the lens**
Patent Assignee: BRONCUS TECHNOLOGIES INC (BRON-N)
Inventor: KEAST T; **TANAKA D** ; THOMPSON D
Number of Countries: 100 Number of Patents: 002
Patent Family:

Patent No	Kind	Date	Applicat No	Kind	Date	Week
US 20020111619	A1	20020815	US 2001269130	P	20010214	200279 B
			US 2001946706	A	20010904	
WO 200269823	A2	20020912	WO 2002US4612	A	20020214	200279

Priority Applications (No Type Date): US 2001269130 P 20010214; US 2001946706 A 20010904
Patent Details:

Patent No	Kind	Lan	Pg	Main IPC	Filing Notes
US 20020111619	A1		56	A61B-018/18	Provisional application US 2001269130
WO 200269823	A2	E		A61B-018/18	

Designated States (National): AE AG AL AM AT AU AZ BA BB BG BR BY BZ CA CH CN CO CR CU CZ DE DK DM DZ EC EE ES FI GB GD GE GH GM HR HU ID IL IN IS JP KE KG KP KR KZ LC LK LR LS LT LU LV MA MD MG MK MN MW MX MZ NO NZ OM PH PL PT RO RU SD SE SG SI SK SL TJ TM TN TR TT TZ UA UG US UZ VN YU ZA ZM ZW
Designated States (Regional): AT BE CH CY DE DK EA ES FI FR GB GH GM GR IE IT KE LS LU MC MW MZ NL OA PT SD SE SL SZ TR TZ UG ZM ZW

Tissue motion detection device for treatment of chronic obstructive pulmonary **disease, has transducer assembly with lens located at distal end of assembly, and heating element...**
...Inventor: **TANAKA D**

Abstract (Basic):
... Tissue motion detection device for treatment of **chronic obstructive pulmonary** disease (**COPD**).

5/3,K/7 (Item 7 from file: 350)
DIALOG(R)File 350:Derwent WPIX

014844782
WPI Acc No: 2002-665488/200271
Related WPI Acc No: 2001-183025; 2002-731244; 2003-090179; 2003-090394; 2003-248441; 2003-256991; 2003-635036; 2003-877133; 2004-059032; 2004-081957; 2004-118964
XRPX Acc No: N02-526464
Medical device for creating collateral channels in lung tissue, has heating element producing heat to create holes in tissue which is minimized radially by heating surface provided on front surface of heating element
Patent Assignee: BRONCUS TECHNOLOGIES INC (BRON-N)
Inventor: HAUGAARD D; KEAST T; ROSCHAK E; **TANAKA D**
Number of Countries: 100 Number of Patents: 004
Patent Family:

Patent No	Kind	Date	Applicat No	Kind	Date	Week
US 20020087153	A1	20020704	US 99147528	P	19990805	200271 B
			US 2000176141	P	20000114	
			US 2000633651	A	20000807	
			US 2001269130	P	20010214	
			US 2001908008	A	20010718	
			US 2001947126	A	20010904	
WO 200264045	A1	20020822	WO 2002US4494	A	20020214	200271
US 6712812	B2	20040330	US 99147528	P	19990805	200423
			US 2000176141	P	20000114	
			US 2000633651	A	20000807	
			US 2001269130	P	20010214	
			US 2001908008	A	20010718	
			US 2001947126	A	20010904	
AU 2002306503	A1	20020828	AU 2002306503	A	20020214	200427

Priority Applications (No Type Date): US 2001947126 A 20010904; US 99147528 P 19990805; US 2000176141 P 20000114; US 2000633651 A 20000807; US 2001269130 P 20010214; US 2001908008 A 20010718

Patent Details:

Patent No	Kind	Lan	Pg	Main IPC	Filing Notes
US 20020087153	A1		57	A61B-018/04	Provisional application US 99147528
					Provisional application US 2000176141
					Cont of application US 2000633651
					Provisional application US 2001269130
					CIP of application US 2001908008
WO 200264045	A1	E		A61B-018/18	
US 6712812	B2			A61B-018/18	Provisional application US 99147528
					Provisional application US 2000176141
					Cont of application US 2000633651
					Provisional application US 2001269130
					CIP of application US 2001908008
AU 2002306503	A1			A61B-018/18	Based on patent WO 200264045

Designated States (National): AE AG AL AM AT AU AZ BA BB BG BR BY BZ CA CH CN CO CR CU CZ DE DK DM DZ EC EE ES FI GB GD GE GH GM HR HU ID IL IN IS JP KE KG KP KR KZ LC LK LR LS LT LU LV MA MD MG MK MN MW MX MZ NO NZ OM PH PL PT RO RU SD SE SG SI SK SL TJ TM TN TR TT TZ UA UG US UZ VN YU ZA ZM ZW

Designated States (Regional): AT BE CH CY DE DK EA ES FI FR GB GH GM GR IE IT KE LS LU MC MW MZ NL OA PT SD SE SL SZ TR TZ UG ZM ZW

...Inventor: **TANAKA D**

Abstract (Basic):

... altering gaseous flow within lungs to improve expiration cycle, for treatment of chronic pulmonary disease (**COPD**), **chronic** lobstructive lung disease (COLD), chronic airflow obstruction (CAO), chronic airflow limitation, using non-invasive imaging such as...

5/3,K/8 (Item 8 from file: 350)

DIALOG(R)File 350:Derwent WPIX

013698801 **Image available**

WPI Acc No: 2001-183025/200118

Related WPI Acc No: 2002-665488; 2002-731244; 2003-090179; 2003-090394; 2003-248441; 2003-256991; 2003-635036; 2003-877133; 2004-059032; 2004-081957; 2004-118964

XRPX Acc No: N01-130611

Gaseous flow altering device has probe to create collateral channel in lung and puncture airway wall in lung, with gas delivery member transferring gas to air sac of lung, and expandable member to occlude airway while probe extends through

Patent Assignee: BRONCUS TECHNOLOGIES INC (BRON-N); COOPER J D (COOP-I); FRENCH G E (FREN-I); HAUGAARD D (HAUG-I); KAPLAN G (KAPL-I); LAUFER M D (LAUF-I); LOOMAS B (LOOM-I); ROSCHAK E (ROSC-I); TANAKA D (TANA-I); THOMPSON D (THOM-I); KEAST T (KEAS-I); ROSS J A (ROSS-I)

Inventor: COOPER J D; DAVENPORT J M; LAUFER M D; LOOMAS B; **TANAKA D** ; THOMPSON D; FRENCH G E; HAUGAARD D; KAPLAN G; ROSCHAK E; KEAST T; ROSS J A

Number of Countries: 095 Number of Patents: 014

Patent Family:

Patent No	Kind	Date	Applicat No	Kind	Date	Week	
WO 200110314	A2	20010215	WO 2000US21637	A	20000807	200118	B
AU 200065308	A	20010305	AU 200065308	A	20000807	200130	
EP 1151729	A1	20011107	EP 2000952649	A	20000807	200168	
			EP 2001113736	A	20000807		
EP 1143864	A2	20011017	EP 2000952649	A	20000807	200169	
			WO 2000US21637	A	20000807		
US 20020042564	A1	20020411	US 99147528	P	19990805	200227	
			US 2000176141	P	20000114		
			US 2000633651	A	20000807		
			US 2001908087	A	20010718		
US 20020042565	A1	20020411	US 99147528	P	19990805	200227	
			US 2000176141	P	20000114		
			US 2000633651	A	20000807		
			US 2001908177	A	20010718		
US 20020049370	A1	20020425	US 99147528	P	19990805	200233	
			US 2000176141	P	20000114		
			US 2000633651	A	20000807		
			US 2001908008	A	20010718		
JP 2003506132	W	20030218	WO 2000US21637	A	20000807	200315	
			JP 2001514843	A	20000807		
US 6629951	B2	20031007	US 99147528	P	19990805	200374	
			US 2000176141	P	20000114		
			US 2000633651	A	20000807		
			US 2001908008	A	20010718		
EP 1143864	B1	20040204	EP 2000952649	A	20000807	200410	
			WO 2000US21637	A	20000807		
			EP 2001113736	A	20000807		
US 6692494	B1	20040217	US 99147528	P	19990805	200413	
			US 2000176141	P	20000114		
			US 2000633651	A	20000807		
DE 60008072	E	20040311	DE 608072	A	20000807	200419	
			EP 2000952649	A	20000807		
			WO 2000US21637	A	20000807		
EP 1400204	A1	20040324	EP 2000952649	A	20000807	200421	
			EP 200324162	A	20000807		
US 20040073201	A1	20040415	US 99147528	P	19990805	200426	
			US 2000176141	P	20000114		
			US 2000633651	A	20000807		
			US 2003633902	A	20030804		

Priority Applications (No Type Date): US 2000176141 P 20000114; US 99147528 P 19990805; US 2000633651 A 20000807; US 2001908087 A 20010718; US 2001908177 A 20010718; US 2001908008 A 20010718; US 2003633902 A 20030804

Patent Details:

Patent No	Kind	Lan	Pg	Main IPC	Filing Notes
WO 200110314	A2	E	102	A61B-017/22	

Designated States (National): AE AG AL AM AT AU AZ BA BB BG BR BY BZ CA

CH CN CR CU CZ DE DK DM DZ EE ES FI GB GD GE GH GM HR HU ID IL IN IS JP
KE KG KP KR KZ LC LK LR LS LT LU LV MA MD MG MK MN MW MX MZ NO NZ PL PT
RO RU SD SE SG SI SK SL TJ TM TR TT TZ UA UG US UZ VN YU ZA ZW
Designated States (Regional): AT BE CH CY DE DK EA ES FI FR GB GH GM GR
IE IT KE LS LU MC MW MZ NL OA PT SD SE SL SZ TZ UG ZW

AU	200065308	A			Based on patent WO 200110314
EP	1151729	A1 E		A61F-002/06	Div ex application EP 2000952649 Div ex patent EP 1143864

Designated States (Regional): AL AT BE CH CY DE DK ES FI FR GB GR IE IT
LI LT LU LV MC MK NL RO SI

EP	1143864	A2 E			Based on patent WO 200110314

Designated States (Regional): AL AT BE CH CY DE DK ES FI FR GB GR IE IT
LI LT LU LV MC MK NL RO SI

US	20020042564	A1		A61B-005/00	Provisional application US 99147528 Provisional application US 2000176141 Cont of application US 2000633651
US	20020042565	A1		A61B-005/00	Provisional application US 99147528 Provisional application US 2000176141 Cont of application US 2000633651
US	20020049370	A1		A61B-017/00	Provisional application US 99147528 Provisional application US 2000176141 Cont of application US 2000633651
JP	2003506132	W	104	A61B-017/02	Based on patent WO 200110314
US	6629951	B2		A61M-029/00	Provisional application US 99147528 Provisional application US 2000176141 Cont of application US 2000633651
EP	1143864	B1 E		A61B-017/22	Related to application EP 2001113736 Related to patent EP 1151729 Based on patent WO 200110314

Designated States (Regional): AT BE CH CY DE DK ES FI FR GB GR IE IT LI
LU MC NL PT SE

US	6692494	B1		A61B-018/18	Provisional application US 99147528 Provisional application US 2000176141
DE	60008072	E		A61B-017/22	Based on patent EP 1143864 Based on patent WO 200110314
EP	1400204	A1 E		A61B-008/06	Div ex application EP 2000952649 Div ex patent EP 1143864

Designated States (Regional): AL AT BE CH CY DE DK ES FI FR GB GR IE IT
LI LT LU LV MC MK NL PT SE

US	20040073201	A1		A61B-018/18	Provisional application US 99147528 Provisional application US 2000176141 Cont of application US 2000633651 Cont of patent US 6692494

...Inventor: **TANAKA D**
...International Patent Class (Main): **A61M-029/00**
...International Patent Class (Additional): **A61M-001/04** ...

... **A61M-029/02** ...

... **A61M-031/00** ...

... **A61M-037/00**

5/3,K/9 (Item 9 from file: 350)
DIALOG(R)File 350:Derwent WPIX

013531335 **Image available**
WPI Acc No: 2001-015541/200102
Related WPI Acc No: 1998-557204; 1999-419226; 1999-457984; 2001-159342; 2001-243621; 2001-564303
XRPX Acc No: N01-011823

Bronchial tube wall treating apparatus for asthma treatment, has electrodes connected to elongated shaft, and tube which is energized by micro waves

Patent Assignee: BRONCUS TECHNOLOGIES INC (BRON-N)
Inventor: BURGER K M; LAUFER M D; LOOMAS B E; **TANAKA D A**
Number of Countries: 090 Number of Patents: 005
Patent Family:

Patent No	Kind	Date	Applicat No	Kind	Date	Week	
WO 200051510	A1	20000908	WO 2000US5412	A	20000301	200102	B
AU 200033903	A	20000921	AU 200033903	A	20000301	200102	
US 6283988	B1	20010904	US 97833550	A	19970407	200154	
			US 983750	A	19980107		
			US 99260401	A	19990301		
EP 1164958	A1	20020102	EP 2000912121	A	20000301	200209	
			WO 2000US5412	A	20000301		
JP 2002537889	W	20021112	JP 2000601983	A	20000301	200275	
			WO 2000US5412	A	20000301		

Priority Applications (No Type Date): US 99260401 A 19990301; US 97833550 A 19970407; US 983750 A 19980107
Patent Details:

Patent No	Kind	Lan	Pg	Main IPC	Filing Notes
WO 200051510	A1	E	28	A61B-018/14	

Designated States (National): AE AL AM AT AU AZ BA BB BG BR BY CA CH CN CR CU CZ DE DK DM EE ES FI GB GD GE GH GM HR HU ID IL IN IS JP KE KG KP KR KZ LC LK LR LS LT LU LV MD MG MK MN MW MX NO NZ PL PT RO RU SD SE SG SI SK SL TJ TM TR TT UA UG US UZ VN YU ZA ZW
Designated States (Regional): AT BE CH CY DE DK EA ES FI FR GB GH GM GR IE IT KE LS LU MC MW NL OA PT SD SE SL SZ TZ UG ZW

AU 200033903	A		A61B-018/14	Based on patent WO 200051510
US 6283988	B1		A61F-002/00	CIP of application US 97833550
				CIP of application US 983750
				CIP of patent US 5972026
EP 1164958	A1	E	A61B-018/14	Based on patent WO 200051510

Designated States (Regional): AL AT BE CH CY DE DK ES FI FR GB GR IE IT LI LT LU LV MC MK NL PT RO SE SI

JP 2002537889	W	33	A61M-029/02	Based on patent WO 200051510

...Inventor: **TANAKA D A**

Abstract (Basic):
... For treatment of airway obstruction found in **chronic obstructive pulmonary** diseases like cystic fibrosis, chronic bronchitis, emphysema, asthma...
...International Patent Class (Main): **A61M-029/02**

5/3,K/10 (Item 10 from file: 350)
DIALOG(R)File 350:Derwent WPIX

012651879 **Image available**
WPI Acc No: 1999-457984/199938
Related WPI Acc No: 1998-557204; 1999-419226; 2000-105837; 2001-015541;

2001-060736; 2001-159342; 2001-243621; 2001-564303; 2002-665659
XRPX Acc No: N99-342588
Bronchial tube treatment apparatus
Patent Assignee: BRONCUS TECHNOLOGIES INC (BRON-N)
Inventor: BURGER K M; LAUFER M D; LOOMAS B E; **TANAKA D A**
Number of Countries: 084 Number of Patents: 003
Patent Family:

Patent No	Kind	Date	Applicat No	Kind	Date	Week
WO 9932040	A1	19990701	WO 98US26227	A	19981221	199938 B
AU 9918144	A	19990712	AU 9918144	A	19981221	199950
US 6083255	A	20000704	US 97833550	A	19970407	200036
			US 97994064	A	19971219	

Priority Applications (No Type Date): US 97994064 A 19971219; US 97833550 A 19970407
Patent Details:

Patent No	Kind	Lan	Pg	Main IPC	Filing Notes
WO 9932040	A1	E	29	A61B-017/36	
AU 9918144	A				Based on patent WO 9932040
US 6083255	A			A61B-017/39	CIP of application US 97833550

Designated States (National): AL AM AT AU AZ BA BB BG BR BY CA CH CN CU CZ DE DK EE ES FI GB GD GE GH GM HR HU ID IL IN IS JP KE KG KP KR KZ LC LK LR LS LT LU LV MD MG MK MN MW MX NO NZ PL PT RO RU SD SE SG SI SK SL TJ TM TR TT UA UG US UZ VN YU ZW
Designated States (Regional): AT BE CH CY DE DK EA ES FI FR GB GH GM GR IE IT KE LS LU MC MW NL OA PT SD SE SZ UG ZW

...Inventor: **TANAKA D A**

Abstract (Basic):
... The apparatus treats collapsed bronchial tubes found in patients with **chronic obstructive pulmonary** disease. The apparatus, which has a balloon (12,100) at a distal end of an...

...The apparatus is used for treatment of the airway obstruction found in **chronic obstructive pulmonary** diseases...

5/3,K/11 (Item 11 from file: 350)
DIALOG(R)File 350:Derwent WPIX

012613122 **Image available**
WPI Acc No: 1999-419226/199935
Related WPI Acc No: 1998-557204; 1999-457984; 2001-015541; 2001-159342; 2001-243621; 2001-564303
XRPX Acc No: N99-312907
Bronchial stenter for heat treating collapsed bronchial tubes in patients with chronic obstructive pulmonary **diseases (COPD)**
Patent Assignee: BRONCUS TECHNOLOGIES INC (BRON-N)
Inventor: BURGER K M; LAUFER M D; LOOMAS B E; **TANAKA D A**
Number of Countries: 084 Number of Patents: 004
Patent Family:

Patent No	Kind	Date	Applicat No	Kind	Date	Week
WO 9934741	A1	19990715	WO 99US232	A	19990107	199935 B
AU 9920275	A	19990726	AU 9920275	A	19990107	199952
US 5972026	A	19991026	US 97833550	A	19970407	199952
			US 983750	A	19980107	
US 6283989	B1	20010904	US 97833550	A	19970407	200154
			US 983750	A	19980107	

Priority Applications (No Type Date): US 983750 A 19980107; US 97833550 A 19970407; US 99280672 A 19990329

Patent Details:

Patent No	Kind	Lan	Pg	Main IPC	Filing Notes
WO 9934741	A1	E	37	A61B-017/36	
Designated States (National): AL AM AT AU AZ BA BB BG BR BY CA CH CN CU CZ DE DK EE ES FI GB GD GE GH GM HR HU ID IL IN IS JP KE KG KP KR KZ LC LK LR LS LT LU LV MD MG MK MN MW MX NO NZ PL PT RO RU SD SE SG SI SK SL TJ TM TR TT UA UG US UZ VN YU ZW					
Designated States (Regional): AT BE CH CY DE DK EA ES FI FR GB GH GM GR IE IT KE LS LU MC MW NL OA PT SD SE SZ UG ZW					
AU 9920275	A			A61B-017/36	Based on patent WO 9934741
US 5972026	A			A61B-017/39	CIP of application US 97833550
US 6283989	B1			A61F-002/00	CIP of application US 97833550 Div ex application US 983750 Div ex patent US 5972026

Bronchial stenter for heat treating collapsed bronchial tubes in patients with chronic obstructive pulmonary **diseases (COPD)**

...Inventor: **TANAKA D A**

Abstract (Basic):

... Treatment of collapsed bronchial tubes in patients with **chronic obstructive pulmonary** diseases (**COPD**), e.g. cystic fibrosis, chronic bronchitis, emphysema and asthma. To modify lung structure (claimed...

```
Set      Items   Description
S1          57   AU=(TANAKA D? OR TANAKA, D?)
S2        4849   OXYGEN(2N)THERAP? OR COPD OR CHRONIC()OBSTRUCT?()(LUNG? OR
                 PULMON?)
S3       32556   IC=A61M?
S4          17   S1 AND S2:S3
S5          17   IDPAT (sorted in duplicate/non-duplicate order)
? show files
File 348:EUROPEAN PATENTS 1978-2004/Apr W04
         (c) 2004 European Patent Office
File 349:PCT FULLTEXT 1979-2002/UB=20040415,UT=20040408
         (c) 2004 WIPO/Univentio
?
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5/3,AU/1 (Item 1 from file: 348)
DIALOG(R)File 348:EUROPEAN PATENTS
(c) 2004 European Patent Office. All rts. reserv.

01710246
Methods and devices for creating collateral channels in the lungs
Verfahren und Vorrichtungen zur Herstellung von kollateralen Kanalen in den Lungen
Procedes et dispositifs permettant de creer des canaux collateraux dans les poumons
PATENT ASSIGNEE:
Broncus Technologies, Inc., (2642920), Building A, Suite 8, 1400 N. Shoreline Boulevard, Mountain View, CA 94043, (US), (Applicant designated States: all)
INVENTOR:
Cooper, Joel, D., 2708 Turnberry Park Lane, St. Louis MO 63131, (US)
Loomas, Bryan, 265 Snow Crest Drive, Los Gatos CA 95033, (US)
Tanaka, Don , 18774 Devon Avenue, Saragota CA 95070, (US)
Laufer, Michael, D, 1259 El Camino Real 211, Menlo Park CA 94025, (US)
Thompson, David, 793 Almondwood Way, San Jose CA 95120, (US)
Davenport, James, M., 1461 Sunset Grove Road, Fallbrook CA 92028, (US
LEGAL REPRESENTATIVE:
Price, Nigel John King (62102), J.A. KEMP & CO. 14 South Square Gray's Inn, London WC1R 5JJ, (GB)
PATENT (CC, No, Kind, Date): EP 1400204 A1 040324 (Basic)
APPLICATION (CC, No, Date): EP 2003024162 000807;
PRIORITY (CC, No, Date): US 147528 P 990805; US 176141 P 000114
DESIGNATED STATES: AT; BE; CH; CY; DE; DK; ES; FI; FR; GB; GR; IE; IT; LI; LU; MC; NL; PT; SE
EXTENDED DESIGNATED STATES: AL; LT; LV; MK
RELATED PARENT NUMBER(S) - PN (AN):
EP 1143864 (EP 2000952649)
INTERNATIONAL PATENT CLASS: A61B-008/06; A61B-008/12; A61B-017/22
ABSTRACT WORD COUNT: 128
NOTE:
Figure number on first page: 6a
LANGUAGE (Publication,Procedural,Application): English; English; English
FULLTEXT AVAILABILITY:

Available Text	Language	Update	Word Count
CLAIMS A	(English)	200413	651
SPEC A	(English)	200413	15397
Total word count - document A			16048
Total word count - document B			0
Total word count - documents A + B			16048

5/3,AU/2 (Item 2 from file: 348)
DIALOG(R)File 348:EUROPEAN PATENTS
(c) 2004 European Patent Office. All rts. reserv.

01349406
Methods and devices for creating collateral channels in the lungs
Verfahren und Vorrichtungen zur Herstellung von kollateralen Kanalen in den Lungen
Procedes et dispositifs permettant de creer des canaux collateraux dans les poumons
PATENT ASSIGNEE:
Broncus Technologies, Inc., (2642920), Building A, Suite 8, 1400 N. Shoreline Boulevard, Mountain View, CA 94043, (US), (Applicant designated States: all)

INVENTOR:
Cooper, Joel D., 2708 Turnberry Park Lane, St. Louis, MO 63131, (US)
Loomas, Bryan, 265 Snow Crest Drive, Los Gatos, CA 95033, (US)
Tanaka, Don , 18774 Devon Avenue, Saratoga, CA 95070, (US)
Laufer, Michael D., 1259 El Camino Real Apt. 211, Menlo Park, CA 94025, (US)
Thompson, David, 793 Almondwood Way, San Jose, CA 95120, (US)
Davenport, James M., 1461 Sunset Grove Road, Fallbrook, CA 92028, (US
LEGAL REPRESENTATIVE:
Price, Nigel John King (62102), J.A. KEMP & CO. 14 South Square Gray's Inn, London WC1R 5JJ, (GB)
PATENT (CC, No, Kind, Date): EP 1151729 A1 011107 (Basic)
APPLICATION (CC, No, Date): EP 2001113736 000807;
PRIORITY (CC, No, Date): US 147528 P 990805; US 176141 P 000114
DESIGNATED STATES: AT; BE; CH; CY; DE; DK; ES; FI; FR; GB; GR; IE; IT; LI; LU; MC; NL
EXTENDED DESIGNATED STATES: AL; LT; LV; MK; RO; SI
RELATED PARENT NUMBER(S) - PN (AN):
EP 1143864 (EP 2000952649)
INTERNATIONAL PATENT CLASS: A61F-002/06
ABSTRACT WORD COUNT: 96
NOTE:
Figure number on first page: 1D
LANGUAGE (Publication,Procedural,Application): English; English; English
FULLTEXT AVAILABILITY:

Available Text	Language	Update	Word Count
CLAIMS A	(English)	200145	1155
SPEC A	(English)	200145	16166
Total word count - document A			17321
Total word count - document B			0
Total word count - documents A + B			17321

5/3,AU/3 (Item 3 from file: 348)
DIALOG(R)File 348:EUROPEAN PATENTS

01266055
METHODS AND DEVICES FOR CREATING COLLATERAL CHANNELS IN THE LUNGS
VERFAHREN UND VORRICHTUNGEN ZUR HERSTELLUNG VON KOLLATERALEN KANALEN IN DEN LUNGEN
PROCEDES ET DISPOSITIFS PERMETTANT DE CREER DES CANAUX COLLATERAUX DANS LES POUMONS
PATENT ASSIGNEE:
Broncus Technologies, Inc., (2642920), Building A, Suite 8, 1400 N. Shoreline Boulevard, Mountain View, CA 94043, (US), (Proprietor designated states: all)
INVENTOR:
COOPER, Joel, D., 2708 Turnberry Park Lane, St. Louis, MO 63131, (US)
LOOMAS, Bryan, 265 Snow Crest Drive, Los Gatos, CA 95033, (US)
TANAKA, Don , 18774 Devon Avenue, Saratoga, CA 95070, (US)
LAUFER, Michael, D., 1259 El Camino Real 211, Menlo Park, CA 94025, (US)
THOMPSON, David, 793 Almondwood Way, San Jose, CA 95120, (US)
DAVENPORT, James, M., 1461 Sunset Grove Road, Fallbrook, CA 92028, (US
LEGAL REPRESENTATIVE:
Price, Nigel John King (62102), J.A. KEMP & CO. 14 South Square Gray's Inn, London WC1R 5JJ, (GB)
PATENT (CC, No, Kind, Date): EP 1143864 A2 011017 (Basic)
EP 1143864 B1 040204
WO 2001010314 010215
APPLICATION (CC, No, Date): EP 2000952649 000807; WO 2000US21637 000807

PRIORITY (CC, No, Date): US 147528 P 990805; US 176141 P 000114
DESIGNATED STATES (Pub A): AT; BE; CH; CY; DE; DK; ES; FI; FR; GB; GR; IE;
IT; LI; LU; MC; NL; (Pub B): AT; BE; CH; CY; DE; DK; ES; FI; FR; GB; GR;
IE; IT; LI; LU; MC; NL; PT; SE
EXTENDED DESIGNATED STATES: AL; LT; LV; MK; RO; SI
RELATED DIVISIONAL NUMBER(S) - PN (AN):
EP 1151729 (EP 2001113736)
(EP 2003024162)
INTERNATIONAL PATENT CLASS: A61B-017/22
NOTE:
No A-document published by EPO
LANGUAGE (Publication,Procedural,Application): English; English; English
FULLTEXT AVAILABILITY:

Available Text	Language	Update	Word Count
CLAIMS B	(English)	200406	975
CLAIMS B	(German)	200406	990
CLAIMS B	(French)	200406	1114
SPEC B	(English)	200406	13059
Total word count - document A			0
Total word count - document B			16138
Total word count - documents A + B			16138

5/3,AU/4 (Item 4 from file: 349)
DIALOG(R)File 349:PCT FULLTEXT

00778406
METHODS AND DEVICES FOR CREATING COLLATERAL CHANNELS IN THE LUNGS
PROCEDES ET DISPOSITIFS PERMETTANT DE CREER DES CANAUX COLLATERAUX DANS LES POUMONS
Patent Applicant/Assignee:
BRONCUS TECHNOLOGIES INC, Building A, Suite 8, 1400 N. Shoreline Boulevard, Mountain View, CA 94043, US, US (Residence), US (Nationality), (For all designated states except: US)
Patent Applicant/Inventor:
COOPER Joel D, 2708 Turnberry Park Lane, St. Louis, MO 63131, US, US (Residence), US (Nationality), (Designated only for: US)
LOOMAS Bryan, 265 Snow Crest Drive, Los Gatos, CA 95033, US, US (Residence), US (Nationality), (Designated only for: US)
TANAKA Don , 18774 Devon Avenue, Saratoga, CA 95070, US, US (Residence), US (Nationality), (Designated only for: US)
LAUFER Michael D, 1259 El Camino Real #211, Menlo Park, CA 94025, US, US (Residence), US (Nationality), (Designated only for: US)
THOMPSON David, 793 Almondwood Way, San Jose, CA 95120, US, US (Residence), US (Nationality), (Designated only for: US)
DAVENPORT James M, 1461 Sunset Grove Road, Fallbrook, CA 92028, US, US (Residence), US (Nationality), (Designated only for: US
Legal Representative:
BAGADE Sanjay S, Morrison & Foerster LLP, 755 Page Mill Road, Palo Alto, CA 94304-1018, US
Patent and Priority Information (Country, Number, Date):
Patent: WO 200110314 A2 20010215 (WO 0110314)
Application: WO 2000US21637 20000807 (PCT/WO US0021637)
Priority Application: US 99147528 19990805; US 2000176141 20000114
Designated States: AE AG AL AM AT AU AZ BA BB BG BR BY BZ CA CH CN CR CU CZ DE DK DM DZ EE ES FI GB GD GE GH GM HR HU ID IL IN IS JP KE KG KP KR KZ LC LK LR LS LT LU LV MA MD MG MK MN MW MX MZ NO NZ PL PT RO RU SD SE SG SI SK SL TJ TM TR TT TZ UA UG US UZ VN YU ZA ZW
(EP) AT BE CH CY DE DK ES FI FR GB GR IE IT LU MC NL PT SE
(OA) BF BJ CF CG CI CM GA GN GW ML MR NE SN TD TG

(AP) GH GM KE LS MW MZ SD SL SZ TZ UG ZW
(EA) AM AZ BY KG KZ MD RU TJ TM
Publication Language: English
Filing Language: English
Fulltext Word Count: 22248

5/3,AU/5 (Item 5 from file: 348)
DIALOG(R)File 348:EUROPEAN PATENTS
(c) 2004 European Patent Office. All rts. reserv.

01576581
CONDUITS HAVING DISTAL CAGE STRUCTURE FOR MAINTAINING COLLATERAL CHANNELS IN TISSUE AND RELATED METHODS
CONDUITS A STRUCTURE DE CAGE DISTALE POUR LE MAINTIEN DE CANAUX COLLATERAUX DANS DES TISSUS ET PROCEDES ASSOCIES
PATENT ASSIGNEE:
Broncus Technologies, Inc., (2642920), Building A, Suite 8, 1400 N. Shoreline Boulevard, Mountain View, CA 94043, (US), (Applicant designated States: all)
INVENTOR:
COOPER, Joel, D., 2708 Turnberry Park Lane, St. Louis, MO 63131, (US)
KEAST, Thomas, 860 Park Drive 3, Mountain View, CA 94040, (US)
LOOMAS, Bryan, 265 Snow Crest Road, Los Gatos, CA 95033, (US)
ROSCHAK, Ed, 26262 Verona Place, Mission Viejo, CA 92692, (US)
KAPLAN, Gary, 111 Caselli Avenue, San Francisco, CA 94114, (US)
SAENZ, Sandra, 786 Hope Street, 3, Mountain View, CA 94041, (US)
COLLINSON, Mike, 230 Winchester Drive, Goleta, CA 93117, (US)
REDMOND, Russ, 1148 North Fairview Avenue, Goleta, CA 93117, (US)
VIDAL, Claude, 5426 San Patricio Drive, Santa Barbara, CA 93111, (US)
CHANDOS, David, 4213 Sirius Avenue, Lompoc, CA 93436, (US)
BIGGS, Michael, 639 Azevedo Court, Santa Clara, CA 95051, (US)
KARABEY, Halil, 4515 Grimsby Drive, San Jose, CA 95130, (US)
TANAKA, Don , 18774 Devon Avenue, Saratoga, CA 95070, (US)
THOMPSON, David, 793 Almondwood Way, San Jose, CA 95120, (US
PATENT (CC, No, Kind, Date): WO 2003020338 030313
APPLICATION (CC, No, Date): EP 2002759555 020904; WO 2002US28237 020904
PRIORITY (CC, No, Date): US 317338 P 010904; US 947144 010904; US 334642 P 011129; US 367436 P 020320; US 374022 P 020419; US 387163 P 020607
DESIGNATED STATES: AT; BE; BG; CH; CY; CZ; DE; DK; EE; ES; FI; FR; GB; GR; IE; IT; LI; LU; MC; NL; PT
EXTENDED DESIGNATED STATES: AL; LT; LV; MK; RO; SI
INTERNATIONAL PATENT CLASS: **A61M-001/00**
LANGUAGE (Publication,Procedural,Application): English; English; English

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5/3,AU/6 (Item 6 from file: 348)
DIALOG(R)File 348:EUROPEAN PATENTS
(c) 2004 European Patent Office. All rts. reserv.

01468500
DEVICES FOR CREATING COLLATERAL CHANNELS
DISPOSITIFS DE CREATION DE CANAUX COLLATERAUX
PATENT ASSIGNEE:
Broncus Technologies, Inc., (2642920), Building A, Suite 8, 1400 N. Shoreline Boulevard, Mountain View, CA 94043, (US), (Applicant designated States: all)
INVENTOR:
COOPER, Joel, D., 2708 Turnberry Park Lane, St. Louis, MO 63131, (US)

DAVENPORT, James, M., 1461 Sunset Grove Road, Fallbrook, CA 92028, (US)
LOOMAS, Bryan, 265 Snow Crest Drive, Los Gatos, CA 95033, (US)
TANAKA, Don , 18774 Devon Avenue, Saratoga, CA 95070, (US)
KAPLAN, Gary, 11 Caselli Avenue, San Francisco, CA 94114, (US
PATENT (CC, No, Kind, Date): WO 2002064190 020822
APPLICATION (CC, No, Date): EP 2002717441 020214; WO 2002US4610 020214
PRIORITY (CC, No, Date): US 269130 P 010214; US 947144 010904
DESIGNATED STATES: AT; BE; CH; CY; DE; DK; ES; FI; FR; GB; GR; IE; IT; LI; LU; MC; NL; PT; SE; TR
EXTENDED DESIGNATED STATES: AL; LT; LV; MK; RO; SI
INTERNATIONAL PATENT CLASS: **A61M-001/00**
LANGUAGE (Publication,Procedural,Application): English; English; English

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5/3,AU/7 (Item 7 from file: 349)
DIALOG(R)File 349:PCT FULLTEXT

00992056
CONDUITS HAVING DISTAL CAGE STRUCTURE FOR MAINTAINING COLLATERAL CHANNELS IN TISSUE AND RELATED METHODS
CONDUITS A STRUCTURE DE CAGE DISTALE POUR LE MAINTIEN DE CANAUX COLLATERAUX DANS DES TISSUS ET PROCEDES ASSOCIES
Patent Applicant/Assignee:
BRONCUS TECHNOLOGIES INC, Building A, Suite 8, 1400 N. Shoreline Blvd, Mountain View, CA 94043, US, US (Residence), US (Nationality), (For all designated states except: US)
Patent Applicant/Inventor:
COOPER Joel D, 2708 Turnberry Park Lane, St. Louis, MO 63131, US, US (Residence), US (Nationality), (Designated only for: US)
KEAST Thomas, 860 Park Drive #3, Mountain View, CA 94040, US, US (Residence), US (Nationality), (Designated only for: US)
LOOMAS Bryan, 265 Snow Crest Road, Los Gatos, CA 95033, US, US (Residence), US (Nationality), (Designated only for: US)
ROSCHAK Ed, 26262 Verona Place, Mission Viejo, CA 92692, US, US (Residence), US (Nationality), (Designated only for: US)
KAPLAN Gary, 111 Caselli Avenue, San Francisco, CA 94114, US, US (Residence), US (Nationality), (Designated only for: US)
SAENZ Sandra, 786 Hope Street, #3, Mountain View, CA 94041, US, US (Residence), US (Nationality), (Designated only for: US)
COLLINSON Mike, 230 Winchester Drive, Goleta, CA 93117, US, US (Residence), US (Nationality), (Designated only for: US)
REDMOND Russ, 1148 North Fairview Avenue, Goleta, CA 93117, US, US (Residence), US (Nationality), (Designated only for: US)
VIDAL Claude, 5426 San Patricio Drive, Santa Barbara, CA 93111, US, US (Residence), US (Nationality), (Designated only for: US)
CHANDOS David, 4213 Sirius Avenue, Lompoc, CA 93436, US, US (Residence), US (Nationality), (Designated only for: US)
BIGGS Michael, 639 Azevedo Court, Santa Clara, CA 95051, US, US (Residence), US (Nationality), (Designated only for: US)
KARABEY Halil, 4515 Grimsby Drive, San Jose, CA 95130, US, US (Residence), US (Nationality), (Designated only for: US)
TANAKA Don , 18774 Devon Avenue, Saratoga, CA 95070, US, US (Residence), US (Nationality), (Designated only for: US)
THOMPSON David, 793 Almondwood Way, San Jose, CA 95120, US, US (Residence), US (Nationality), (Designated only for: US
Legal Representative:
BATT Richard R (et al) (agent), Morrison & Foerster LLP, 755 Page Mill Road, Palo Alto, CA 94304-1018, US,
Patent and Priority Information (Country, Number, Date):

Patent: WO 200320338 A2-A3 20030313 (WO 0320338)
Application: WO 2002US28237 20020904 (PCT/WO US2002028237)
Priority Application: US 2001317338 20010904; US 2001947144 20010904; US 2001334642 20011129; US 2002367436 20020320; US 2002374022 20020419; US 2002387163 20020607
Designated States: AE AG AL AM AT AU AZ BA BB BG BR BY BZ CA CH CN CO CR CU CZ DE DK DM DZ EC EE ES FI GB GD GE GH GM HR HU ID IL IN IS JP KE KG KP KR KZ LC LK LR LS LT LU LV MA MD MG MK MN MW MX MZ NO NZ OM PH PL PT RO RU SD SE SG SI SK SL TJ TM TN TR TT TZ UA UG US UZ VN YU ZA ZM ZW
(EP) AT BE BG CH CY CZ DE DK EE ES FI FR GB GR IE IT LU MC NL PT SE SK TR
(OA) BF BJ CF CG CI CM GA GN GQ GW ML MR NE SN TD TG
(AP) GH GM KE LS MW MZ SD SL SZ TZ UG ZM ZW
(EA) AM AZ BY KG KZ MD RU TJ TM
Publication Language: English
Filing Language: English
Fulltext Word Count: 22563

5/3,AU/8 (Item 8 from file: 349)

00931844

DEVICES FOR CREATING COLLATERAL CHANNELS
DISPOSITIFS DE CREATION DE CANAUX COLLATERAUX

Patent Applicant/Assignee:
BRONCUS TECHNOLOGIES INC, Building A, Suite 8, 1400 Shoreline Blvd., Mountain View, CA 94043, US, US (Residence), US (Nationality), (For all designated states except: US)

Patent Applicant/Inventor:
COOPER Joel D, 2708 Turnberry Park Lane, St. Louis, MO 63131, US, US (Residence), US (Nationality), (Designated only for: US)
DAVENPORT James M, 1461 Sunset Grove Road, Fallbrook, CA 92028, US, US (Residence), US (Nationality), (Designated only for: US)
LOOMAS Bryan, 265 Snow Crest Drive, Los Gatos, CA 95033, US, US (Residence), US (Nationality), (Designated only for: US)
TANAKA Don , 18774 Devon Avenue, Saratoga, CA 95070, US, US (Residence), US (Nationality), (Designated only for: US)
KAPLAN Gary, 11 Caselli Avenue, San Francisco, CA 94114, US, US (Residence), US (Nationality), (Designated only for: US

Legal Representative:
BATT Richard R (et al) (agent), Morrison & Foerster LLP, 755 Page Mill Road, Palo Alto, CA 94304-1018, US,

Patent and Priority Information (Country, Number, Date):
Patent: WO 200264190 A2-A3 20020822 (WO 0264190)
Application: WO 2002US4610 20020214 (PCT/WO US0204610)
Priority Application: US 2001269130 20010214; US 2001947144 20010904
Designated States: AE AG AL AM AT AU AZ BA BB BG BR BY BZ CA CH CN CO CR CU CZ DE DK DM DZ EC EE ES FI GB GD GE GH GM HR HU ID IL IN IS JP KE KG KP KR KZ LC LK LR LS LT LU LV MA MD MG MK MN MW MX MZ NO NZ OM PH PL PT RO RU SD SE SG SI SK SL TJ TM TN TR TT TZ UA UG US UZ VN YU ZA ZM ZW
(EP) AT BE CH CY DE DK ES FI FR GB GR IE IT LU MC NL PT SE TR
(OA) BF BJ CF CG CI CM GA GN GQ GW ML MR NE SN TD TG
(AP) GH GM KE LS MW MZ SD SL SZ TZ UG ZM ZW
(EA) AM AZ BY KG KZ MD RU TJ TM
Publication Language: English
Filing Language: English
Fulltext Word Count: 20347

5/3,AU/9 (Item 9 from file: 348)

DIALOG(R)File 348:EUROPEAN PATENTS
(c) 2004 European Patent Office. All rts. reserv.

01701656
Fluid trap system
Flussigkeitsfalle
Systeme de piege a liquides
PATENT ASSIGNEE:
Cordis Corporation, (280674), 14201 N.W. 60th Avenue, Miami Lakes Florida 33014, (US), (Applicant designated States: all)
INVENTOR:
Tanaka, Don , 18774 Devon Avenue, Saratoga, CA 95070, (US
LEGAL REPRESENTATIVE:
Belcher, Simon James (58311), Urquhart-Dykes & Lord Tower North Central Merrion Way, Leeds LS2 8PA, (GB)
PATENT (CC, No, Kind, Date): EP 1393760 A1 040303 (Basic)
APPLICATION (CC, No, Date): EP 2003255306 030827;
PRIORITY (CC, No, Date): US 406624 P 020828; US 613860 P 030703
DESIGNATED STATES: AT; BE; BG; CH; CY; CZ; DE; DK; EE; ES; FI; FR; GB; GR; HU; IE; IT; LI; LU; MC; NL; PT; RO; SE; SI; SK; TR
EXTENDED DESIGNATED STATES: AL; LT; LV; MK
INTERNATIONAL PATENT CLASS: **A61M-001/00** ; **A61M-016/10**
ABSTRACT WORD COUNT: 127
NOTE:
Figure number on first page: NONE
LANGUAGE (Publication,Procedural,Application): English; English; English
FULLTEXT AVAILABILITY:

Available Text	Language	Update	Word Count
CLAIMS A	(English)	200410	190
SPEC A	(English)	200410	6886
Total word count - document A			7076
Total word count - document B			0
Total word count - documents A + B			7076

5/3,AU/10 (Item 10 from file: 348)
DIALOG(R)File 348:EUROPEAN PATENTS
(c) 2004 European Patent Office. All rts. reserv.

01691994
Long term oxygen therapy **system**
System fur langandauernde Sauerstofftherapie
Systeme pour une oxygenotherapie de longue duree
PATENT ASSIGNEE:
Cordis Corporation, (280674), 14201 N.W. 60th Avenue, Miami Lakes Florida 33014, (US), (Applicant designated States: all)
INVENTOR:
Tanaka, Don , 18774 Devon Avenue, Saratoga, CA 95070, (US
LEGAL REPRESENTATIVE:
Belcher, Simon James (58311), Urquhart-Dykes & Lord Tower North Central Merrion Way, Leeds LS2 8PA, (GB)
PATENT (CC, No, Kind, Date): EP 1386635 A1 040204 (Basic)
APPLICATION (CC, No, Date): EP 2003254748 030729;
PRIORITY (CC, No, Date): US 399907 P 020731; US 613358 030703
DESIGNATED STATES: AT; BE; BG; CH; CY; CZ; DE; DK; EE; ES; FI; FR; GB; GR; HU; IE; IT; LI; LU; MC; NL; PT; RO; SE; SI; SK; TR
EXTENDED DESIGNATED STATES: AL; LT; LV; MK
INTERNATIONAL PATENT CLASS: **A61M-037/00** ; **A61M-031/00** ; **A61M-016/00**
ABSTRACT WORD COUNT: 76
NOTE:

Figure number on first page: 1
LANGUAGE (Publication,Procedural,Application): English; English; English
FULLTEXT AVAILABILITY:

Available Text	Language	Update	Word Count
CLAIMS A	(English)	200406	380
SPEC A	(English)	200406	4851
Total word count - document A			5231
Total word count - document B			0
Total word count - documents A + B			5231

5/3,AU/11 (Item 11 from file: 349)
DIALOG(R)File 349:PCT FULLTEXT

01060498
DEVICES FOR MAINTAINING SURGICALLY CREATED OPENINGS
DISPOSITIF DE MAINTIEN D'OUVERTURES CHIRURGICALES
Patent Applicant/Assignee:
BRONCUS TECHNOLOGIES INC, 1400 N. Shoreline Blvd, Building A, Suite 8, Mountain View, CA 94043, US, US (Residence), US (Nationality), (For all designated states except: US)
Patent Applicant/Inventor:
BIGGS Michael, 639 Azevedo Court, Santa Clara, CA 95051, US, US (Residence), US (Nationality), (Designated only for: US)
KEAST Thomas, 1343 Sandia Avenue, Sunnyvale, CA 94089, US, US (Residence), US (Nationality), (Designated only for: US)
LOOMAS Bryan Eugene, 265 Snow Crest Road, Los Gatos, CA 95033, US, US (Residence), US (Nationality), (Designated only for: US)
TANAKA Don , 18744 Devon Avenue, Saratoga, CA 95070, US, US (Residence), US (Nationality), (Designated only for: US)
THOMPSON David, 793 Almondwood Way, San Jose, CA 95120, US, US (Residence), US (Nationality), (Designated only for: US)
KAPLAN Gary S, 111 Caselli Avenue, San Francisco, CA 94114, US, US (Residence), US (Nationality), (Designated only for: US)
SHRINER Kelly M, 191 Highland Avenue, Arlington, MA 02476, US, US (Residence), US (Nationality), (Designated only for: US)
KARABEY Halil, 4515 Grimsby Drive, San Jose, CA 95130, US, US (Residence), US (Nationality), (Designated only for: US)
REDMOND Russell J, 1148 N. Fairview Avenue, Goleta, CA 93117, US, US (Residence), US (Nationality), (Designated only for: US)
COLLINSON Michael, 230 Winchester Drive, Goleta, CA 93117, US, US (Residence), US (Nationality), (Designated only for: US)
CHANDOS David, 4213 Sirius Avenue, Lompoc, CA 93436, US, US (Residence), US (Nationality), (Designated only for: US)
COLE Cary, 2640 Miller Avenue, Mountain View, CA 94040, US, US (Residence), US (Nationality), (Designated only for: US)
WILLINK Michael P, 5488 Mesa Road, Gilroy, CA 95020, US, US (Residence), US (Nationality), (Designated only for: US
Legal Representative:
HAN Johney U (agent), Morrison & Foerster LLP, 755 Page Mill Road, Palo Alto, CA 94304-1018, US,
Patent and Priority Information (Country, Number, Date):
Patent: WO 200388820 A2 20031030 (WO 0388820)
Application: WO 2003US12323 20030421 (PCT/WO US03012323)
Priority Application: US 2002374022 20020419; US 2002387163 20020607; US 2002393629 20020703
Designated States: AE AG AL AM AT AU AZ BA BB BG BR BY BZ CA CH CN CO CR CU CZ DE DK DM DZ EC EE ES FI GB GD GE GH GM HR HU ID IL IN IS JP KE KG KP KR KZ LC LK LR LS LT LU LV MA MD MG MK MN MW MX MZ NI NO NZ OM PH PL PT RO RU SC SD SE SG SK SL TJ TM TN TR TT TZ UA UG US UZ VC VN YU ZA ZM ZW

(EP) AT BE BG CH CY CZ DE DK EE ES FI FR GB GR HU IE IT LU MC NL PT RO SE SI SK TR
(OA) BF BJ CF CG CI CM GA GN GQ GW ML MR NE SN TD TG
(AP) GH GM KE LS MW MZ SD SL SZ TZ UG ZM ZW
(EA) AM AZ BY KG KZ MD RU TJ TM
Publication Language: English
Filing Language: English
Fulltext Word Count: 15964

5/3,AU/12 (Item 12 from file: 349)
DIALOG(R)File 349:PCT FULLTEXT

01043805
DEVICES FOR APPLYING ENERGY TO TISSUE
DISPOSITIFS DESTINES A APPLIQUER DE L'ENERGIE SUR UN TISSU
Patent Applicant/Assignee:
BRONCUS TECHNOLOGIES INC, 1400 N. Shoreline Blvd., Building A, Suite 8, Mountain View, CA 94043, US, US (Residence), US (Nationality), (For all designated states except: US)
Patent Applicant/Inventor:
ROSCHAK Ed, 26262 Verona Place, Mission Viejo, CA 92692, US, US (Residence), US (Nationality), (Designated only for: US)
KEAST Thomas, 860 Park Drive #3, Mountain View, CA 94040, US, US (Residence), US (Nationality), (Designated only for: US)
MELTON Hewlett E Jr, 1138 Royal Ann Drive, Sunnyvale, CA 94087, US, US (Residence), US (Nationality), (Designated only for: US)
WILLINK Christopher Lee, 126 Ada Avenue, Mountain View, CA 94043, US, US (Residence), US (Nationality), (Designated only for: US)
HAUGAARD Dave, 750 Pershing Avenue, San Jose, CA 95126, US, US (Residence), US (Nationality), (Designated only for: US)
THOMPSON David, 793 Almondwood Way, San Jose, CA 95120, US, US (Residence), US (Nationality), (Designated only for: US)
TOM Curtis P, 2237 Bunker Hill Drive, San Mateo, CA 94402, US, US (Residence), US (Nationality), (Designated only for: US)
KRAMER Thomas A, 1149 Orange Avenue, San Carlos, CA 94070, US, US (Residence), US (Nationality), (Designated only for: US)
TANAKA Don , 18744 Devon Avenue, Saratoga, CA 95070, US, US (Residence), US (Nationality), (Designated only for: US
Legal Representative:
HAN Johney U (et al) (agent), Morrison & Foerster LLP, 755 Page Mill Road, Palo Alto, CA 94304-1018, US,
Patent and Priority Information (Country, Number, Date):
Patent: WO 200371924 A2 20030904 (WO 0371924)
Application: WO 2003US4970 20030221 (PCT/WO US0304970)
Priority Application: US 200280344 20020221; US 2002280851 20021025
Designated States: AE AG AL AM AT AU AZ BA BB BG BR BY BZ CA CH CN CO CR CU CZ DE DK DM DZ EC EE ES FI GB GD GE GH GM HR HU ID IL IN IS JP KE KG KP KR KZ LC LK LR LS LT LU LV MA MD MG MK MN MW MX MZ NO NZ OM PH PL PT RO RU SC SD SE SG SK SL TJ TM TN TR TT TZ UA UG US UZ VC VN YU ZA ZM ZW
(EP) AT BE BG CH CY CZ DE DK EE ES FI FR GB GR HU IE IT LU MC NL PT SE SI SK TR
(OA) BF BJ CF CG CI CM GA GN GQ GW ML MR NE SN TD TG
(AP) GH GM KE LS MW MZ SD SL SZ TZ UG ZM ZW
(EA) AM AZ BY KG KZ MD RU TJ TM
Publication Language: English
Filing Language: English
Fulltext Word Count: 18568

5/3,AU/13 (Item 13 from file: 349)
DIALOG(R)File 349:PCT FULLTEXT
(c) 2004 WIPO/Univentio. All rts. reserv.

00937677
DEVICES FOR CREATING COLLATERAL CHANNELS
DISPOSITIFS DE CREATION DE CANAUX COLLATERAUX
Patent Applicant/Assignee:
BRONCUS TECHNOLOGIES INC, 1400 N. Shoreline Blvd, Building A, Suite 8, Mountain View, CA 94043, US, US (Residence), US (Nationality), (For all designated states except: US)
Patent Applicant/Inventor:
KEAST Thomas, 860 Park Drive #3, Mountain View, CA 94040, US, US (Residence), US (Nationality), (Designated only for: US)
THOMPSON David, 793 Almondwood Way, San Jose, CA 95120, US, US (Residence), US (Nationality), (Designated only for: US)
TANAKA Don , 18774 Devon Avenue, Saratoga, CA 95070, US, US (Residence), US (Nationality), (Designated only for: US
Legal Representative:
BATT Richard R (et al) (agent), Morrison & Foerster LLP, 755 Page Mill Road, Palo Alto, CA 94304-1018, US,
Patent and Priority Information (Country, Number, Date):
Patent: WO 200269823 A2-A3 20020912 (WO 0269823)
Application: WO 2002US4612 20020214 (PCT/WO US0204612)
Priority Application: US 2001269130 20010214; US 2001946706 20010904
Designated States: AE AG AL AM AT AU AZ BA BB BG BR BY BZ CA CH CN CO CR CU CZ DE DK DM DZ EC EE ES FI GB GD GE GH GM HR HU ID IL IN IS JP KE KG KP KR KZ LC LK LR LS LT LU LV MA MD MG MK MN MW MX MZ NO NZ OM PH PL PT RO RU SD SE SG SI SK SL TJ TM TN TR TT TZ UA UG US UZ VN YU ZA ZM ZW
(EP) AT BE CH CY DE DK ES FI FR GB GR IE IT LU MC NL PT SE TR
(OA) BF BJ CF CG CI CM GA GN GQ GW ML MR NE SN TD TG
(AP) GH GM KE LS MW MZ SD SL SZ TZ UG ZM ZW
(EA) AM AZ BY KG KZ MD RU TJ TM
Publication Language: English
Filing Language: English
Fulltext Word Count: 19574

5/3,AU/14 (Item 14 from file: 349)
DIALOG(R)File 349:PCT FULLTEXT
(c) 2004 WIPO/Univentio. All rts. reserv.

00930374
DEVICES FOR CREATING COLLATERAL CHANNELS
DISPOSITIFS SERVANT A CREER DES CANAUX COLLATERAUX
Patent Applicant/Assignee:
BRONCUS TECHNOLOGIES INC, 1400 N. Shoreline Blvd, Building A, Suite 8, Mountain View, CA 94043, US, US (Residence), US (Nationality), (For all designated states except: US)
Patent Applicant/Inventor:
ROSCHAK Ed, 430 Whisman Court, Mountain View, CA 94043, US, US (Residence), US (Nationality), (Designated only for: US)
TANAKA Don , 18774 Devon Avenue, Saratoga, CA 95070, US, US (Residence), US (Nationality), (Designated only for: US)
HAUGAARD Dave, 750 Pershing Avenue, San Jose, CA 95126, US, US (Residence), US (Nationality), (Designated only for: US)
KEAST Thomas, 860 Park Drive #3, Mountain View, CA 94040, US, US (Residence), US (Nationality), (Designated only for: US
Legal Representative:
BATT Richard R (et al) (agent), Morrison & Foerster LLP, 755 Page Mill Road, Palo Alto, CA 94304-1018, US,

Patent and Priority Information (Country, Number, Date):
  Patent: WO 200264045 A1 20020822 (WO 0264045)
  Application: WO 2002US4494 20020214 (PCT/WO US0204494)
  Priority Application: US 2001269130 20010214; US 2001947126 20010904
Designated States: AE AG AL AM AT AU AZ BA BB BG BR BY BZ CA CH CN CO CR CU
  CZ DE DK DM DZ EC EE ES FI GB GD GE GH GM HR HU ID IL IN IS JP KE KG KP
  KR KZ LC LK LR LS LT LU LV MA MD MG MK MN MW MX MZ NO NZ OM PH PL PT RO
  RU SD SE SG SI SK SL TJ TM TN TR TT TZ UA UG US UZ VN YU ZA ZM ZW
  (EP) AT BE CH CY DE DK ES FI FR GB GR IE IT LU MC NL PT SE TR
  (OA) BF BJ CF CG CI CM GA GN GQ GW ML MR NE SN TD TG
  (AP) GH GM KE LS MW MZ SD SL SZ TZ UG ZM ZW
  (EA) AM AZ BY KG KZ MD RU TJ TM
Publication Language: English
Filing Language: English
Fulltext Word Count: 20469

5/3,AU/15 (Item 15 from file: 349)
DIALOG(R)File 349:PCT FULLTEXT

00738500
BRONCHIAL STENTER HAVING EXPANDABLE ELECTRODES
EXTENSEUR BRONCHIQUE COMPORTANT DES ELECTRODES EXPANSIBLES
Patent Applicant/Assignee:
  BRONCUS TECHNOLOGIES INC, Building A, Suite 8, 1400 N. Shoreline Boulevard, Mountain View, CA 94043, US, US (Residence), US (Nationality), (For all designated states except: US)
Patent Applicant/Inventor:
  LAUFER Michael D, 1259 El Camino Real, #221, Menlo Park, CA 94025, US, US (Residence), US (Nationality), (Designated only for: US)
  BURGER Keith M, 1856 Franklin Street, #2, San Francisco, CA 94109, US, US (Residence), US (Nationality), (Designated only for: US)
  LOOMAS Bryan E, 13125 Kevin Street, Saratoga, CA 95070, US, US (Residence), US (Nationality), (Designated only for: US)
  TANAKA Don A , 432 North 15th Street, San Jose, CA 95112, US, US (Residence), US (Nationality), (Designated only for: US
Legal Representative:
  BAGADE Sanjay S, Morrison & Foerster LLP, 755 Page Mill Road, Palo Alto, CA 94304-1018, US
Patent and Priority Information (Country, Number, Date):
  Patent: WO 200051510 A1 20000908 (WO 0051510)
  Application: WO 2000US5412 20000301 (PCT/WO US0005412)
  Priority Application: US 99260401 19990301
Designated States: AE AL AM AT AU AZ BA BB BG BR BY CA CH CN CR CU CZ DE DK
  DM EE ES FI GB GD GE GH GM HR HU ID IL IN IS JP KE KG KP KR KZ LC LK LR
  LS LT LU LV MD MG MK MN MW MX NO NZ PL PT RO RU SD SE SG SI SK SL TJ TM
  TR TT UA UG US UZ VN YU ZA ZW
  (EP) AT BE CH CY DE DK ES FI FR GB GR IE IT LU MC NL PT SE
  (OA) BF BJ CF CG CI CM GA GN GW ML MR NE SN TD TG
  (AP) GH GM KE LS MW SD SL SZ TZ UG ZW
  (EA) AM AZ BY KG KZ MD RU TJ TM
Publication Language: English
Filing Language: English
Fulltext Word Count: 7077

5/3,AU/16 (Item 16 from file: 349)
DIALOG(R)File 349:PCT FULLTEXT

00503389
BRONCHIAL STENTER HAVING DIAMETRICALLY ADJUSTABLE ELECTRODES
EXTENSEUR BRONCHIQUE A ELECTRODES DE DIAMETRE REGLABLE
Patent Applicant/Assignee:
BRONCUS TECHNOLOGIES INC,
LAUFER Michael D,
TANAKA Don A,
LOOMAS Bryan E,
BURGER Keith M,
Inventor(s):
LAUFER Michael D,
TANAKA Don A ,
LOOMAS Bryan E,
BURGER Keith M
Patent and Priority Information (Country, Number, Date):
Patent: WO 9934741 A1 19990715
Application: WO 99US232 19990107 (PCT/WO US9900232)
Priority Application: US 983750 19980107
Designated States: AL AM AT AU AZ BA BB BG BR BY CA CH CN CU CZ DE DK EE ES
FI GB GD GE GH GM HR HU ID IL IN IS JP KE KG KP KR KZ LC LK LR LS LT LU
LV MD MG MK MN MW MX NO NZ PL PT RO RU SD SE SG SI SK SL TJ TM TR TT UA
UG US UZ VN YU ZW GH GM KE LS MW SD SZ UG ZW AM AZ BY KG KZ MD RU TJ TM
AT BE CH CY DE DK ES FI FR GB GR IE IT LU MC NL PT SE BF BJ CF CG CI CM
GA GN GW ML MR NE SN TD TG
Publication Language: English
Fulltext Word Count: 8592

5/3,AU/17 (Item 17 from file: 349)
DIALOG(R)File 349:PCT FULLTEXT

00500688
BRONCHIAL STENTER
EXTENSEUR BRONCHIQUE
Patent Applicant/Assignee:
BRONCUS TECHNOLOGIES INC,
LAUFER Michael D,
TANAKA Donald A,
LOOMAS Bryan E,
BURGER Keith M,
Inventor(s):
LAUFER Michael D,
TANAKA Donald A ,
LOOMAS Bryan E,
BURGER Keith M
Patent and Priority Information (Country, Number, Date):
Patent: WO 9932040 A1 19990701
Application: WO 98US26227 19981221 (PCT/WO US9826227)
Priority Application: US 97994064 19971219
Designated States: AL AM AT AU AZ BA BB BG BR BY CA CH CN CU CZ DE DK EE ES
FI GB GD GE GH GM HR HU ID IL IN IS JP KE KG KP KR KZ LC LK LR LS LT LU
LV MD MG MK MN MW MX NO NZ PL PT RO RU SD SE SG SI SK SL TJ TM TR TT UA
UG US UZ VN YU ZW GH GM KE LS MW SD SZ UG ZW AM AZ BY KG KZ MD RU TJ TM
AT BE CH CY DE DK ES FI FR GB GR IE IT LU MC NL PT SE BF BJ CF CG CI CM
GA GN GW ML MR NE SN TD TG
Publication Language: English
Fulltext Word Count: 6252

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Set      Items   Description
S1        1395   AU=(TANAKA D? OR TANAKA, D?)
S2      117610   OXYGEN(2N)THERAP? OR COPD OR CHRONIC()OBSTRUCT?()(LUNG? OR
            PULMON?)
S3          18   S1 AND S2
S4          11   RD (unique items)
? show files
File 155:MEDLINE(R) 1966-2004/Apr W4
         (c) format only 2004 The Dialog Corp.
File   2:INSPEC 1969-2004/Apr W4
         (c) 2004 Institution of Electrical Engineers
File   5:Biosis Previews(R) 1969-2004/Apr W4
         (c) 2004 BIOSIS
File   6:NTIS 1964-2004/May W1
         (c) 2004 NTIS, Intl Cpyrght All Rights Res
File   8:Ei Compendex(R) 1970-2004/Apr W3
         (c) 2004 Elsevier Eng.  Info. Inc.
File  34:SciSearch(R) Cited Ref Sci 1990-2004/Apr W4
         (c) 2004 Inst for Sci Info
File 434:SciSearch(R) Cited Ref Sci 1974-1989/Dec
         (c) 1998 Inst for Sci Info
File  73:EMBASE 1974-2004/Apr W4
         (c) 2004 Elsevier Science B.V.
File  71:ELSEVIER BIOBASE 1994-2004/Apr W3
         (c) 2004  Elsevier Science B.V.
File 144:Pascal 1973-2004/Apr W4
         (c) 2004 INIST/CNRS
File  35:Dissertation Abs Online 1861-2004/Apr
         (c) 2004 ProQuest Info&Learning
File  65:Inside Conferences 1993-2004/Apr W4
         (c) 2004 BLDSC all rts. reserv.
File  94:JICST-EPlus 1985-2004/Apr W2
         (c)2004 Japan Science and Tech Corp(JST)
File  95:TEME-Technology & Management 1989-2004/Apr W2
         (c) 2004 FIZ TECHNIK
File  99:Wilson Appl. Sci & Tech Abs 1983-2004/Mar
         (c) 2004 The HW Wilson Co.
File 481:DELPHES Eur Bus 95-2004/Apr W3
         (c) 2004 ACFCI & Chambre CommInd Paris
File 583:Gale Group Globalbase(TM) 1986-2002/Dec 13
         (c) 2002 The Gale Group
?
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4/3,K/1 (Item 1 from file: 155)
DIALOG(R)File 155:MEDLINE(R)

13564358 PMID: 9245668
Is screening for chronic obstructive pulmonary **disease justified?**
Badgett R G; **Tanaka D J**
Department of Internal Medicine, University of Texas Health Science Center at San Antonio 78284, USA. Badgett@UTHSCSA.edu
Preventive medicine (UNITED STATES) Jul-Aug 1997, 26 (4) p466-72, ISSN 0091-7435 Journal Code: 0322116
Document type: Journal Article; Review; Review, Tutorial
Languages: ENGLISH
Main Citation Owner: NLM
Record type: Completed

Is screening for chronic obstructive pulmonary **disease justified?**
Badgett R G; **Tanaka D J**
BACKGROUND: Many experts recommend spirometry to screen for **chronic obstructive pulmonary** disease (**COPD**) in asymptomatic patients; however, evidence for this recommendation has not been systematically reviewed. METHODS: We...

... search of the CITATION index, to locate randomized trials of interventions for asymptomatic patients with **COPD** . In regard to smoking cessation, we included all controlled trials of smoking cessation programs that...

... versus those who did not. RESULTS: With the exception of smoking cessation, all interventions for **COPD** have only been proven effective in symptomatic patients. Two studies found that multifaceted smoking cessation ...

4/3,K/2 (Item 2 from file: 155)
DIALOG(R)File 155:MEDLINE(R)

09603431 PMID: 8430714
Can moderate chronic obstructive pulmonary **disease be diagnosed by historical and physical findings alone?**
Badgett R G; **Tanaka D J** ; Hunt D K; Jelley M J; Feinberg L E; Steiner J F; Petty T L
Department of Medicine, University of Colorado Health Sciences Center, Denver.
American journal of medicine (UNITED STATES) Feb 1993, 94 (2) p188-96, ISSN 0002-9343 Journal Code: 0267200
Document type: Journal Article
Languages: ENGLISH
Main Citation Owner: NLM
Record type: Completed

Can moderate chronic obstructive pulmonary **disease be diagnosed by historical and physical findings alone?**
Badgett R G; **Tanaka D J** ; Hunt D K; Jelley M J; Feinberg L E; Steiner J F; Petty...
BACKGROUND: The value of the history and physical examination in diagnosing **chronic obstructive pulmonary** disease (**COPD**) is uncertain. This study was undertaken to determine the best clinical predictors of **COPD** and to define the incremental changes in the ability

to diagnose **COPD** that occur when the physical examination findings and then the peak flowmeter results are added...

... SUBJECTS AND METHODS: Ninety-two outpatients with a self-reported history of cigarette smoking or **COPD** completed a pulmonary history questionnaire and received peak flow and spirometric testing. The subjects were...

... internists blinded to all other results. Multivariate analyses identified independent predictors of clinically significant, moderate **COPD** , defined as a forced expiratory volume in 1 second (FEV1) less than 60% of the...

... a FEV1/FVC (forced vital capacity) less than 60%. RESULTS: Fifteen subjects (16%) had moderate **COPD** . Two historical variables from the questionnaire--previous diagnosis of **COPD** and smoking (70 or more pack-years)--significantly entered a logistic regression model that diagnosed **COPD** with a sensitivity of 40% and a specificity of 100%. Only the physical sign of...

... Subjects with none of the three historical and physical variables had a 3% prevalence of **COPD** ; this prevalence was unchanged by adding the peak flow results. CONCLUSIONS: Diminished breath sounds were the best predictor of moderate **COPD** . A sequential increase in sensitivity and a minimal decrease in specificity occurred when the quality...

... added first to the medical history, followed by the peak flow result. The chance of **COPD** was very unlikely with a normal history and physical examination.

4/3,K/3 (Item 1 from file: 5)
DIALOG(R)File 5:Biosis Previews(R)

0014775990 BIOSIS NO.: 200400156747
Methods and devices for creating collateral channels in the lungs
AUTHOR: Cooper Joel D (Reprint); Loomas Bryan; **Tanaka Don** ; Laufer Michael D; Thompson David; Davenport James M; Kaplan Gary; Haugaard Dave; French Glendon E
AUTHOR ADDRESS: St. Louis, MO, USA**USA
JOURNAL: Official Gazette of the United States Patent and Trademark Office Patents 1279 (3): Feb. 17, 2004 2004
MEDIUM: e-file
PATENT NUMBER: US 6692494 PATENT DATE GRANTED: February 17, 2004 20040217
PATENT CLASSIFICATION: 606-46 PATENT ASSIGNEE: Broncus Technologies, Inc.
PATENT COUNTRY: USA
ISSN: 0098-1133 (ISSN print)
DOCUMENT TYPE: Patent
RECORD TYPE: Abstract
LANGUAGE: English

...AUTHOR: **Tanaka Don**

...ABSTRACT: flow within a lung to improve the expiration cycle of, for instance, an individual having **Chronic Obstructive Pulmonary** Disease. More particularly, these devices and methods produce and to maintain collateral openings or channels...
DESCRIPTORS:
DISEASES: **chronic obstructive pulmonary** disease...

4/3,K/4 (Item 2 from file: 5)
DIALOG(R)File 5:Biosis Previews(R)
(c) 2004 BIOSIS. All rts. reserv.

0014553926 BIOSIS NO.: 200300522645
Devices for creating collateral in the lungs
AUTHOR: Laufer Michael D (Reprint); Roschak Ed; **Tanaka Don**
AUTHOR ADDRESS: Mountain View, CA, USA**USA
JOURNAL: Official Gazette of the United States Patent and Trademark Office Patents 1275 (1): Oct. 7, 2003 2003
MEDIUM: e-file
PATENT NUMBER: US 6629951 PATENT DATE GRANTED: October 07, 2003 20031007
PATENT CLASSIFICATION: 604-9601 PATENT ASSIGNEE: Broncus Technologies, Inc. PATENT COUNTRY: USA
ISSN: 0098-1133 (ISSN print)
DOCUMENT TYPE: Patent
RECORD TYPE: Abstract
LANGUAGE: English

...AUTHOR: **Tanaka Don**

...ABSTRACT: flow within a lung to improve the expiration cycle of, for instance, an individual having **Chronic Obstructive Pulmonary** Disease. More particularly, these devices and methods produce and to maintain collateral openings or channels...
DESCRIPTORS:
DISEASES: **chronic obstructive pulmonary** disease...

4/3,K/5 (Item 3 from file: 5)
DIALOG(R)File 5:Biosis Previews(R)
(c) 2004 BIOSIS. All rts. reserv.

0013347005 BIOSIS NO.: 200100518844
Method of treating a bronchial tube with a bronchial stenter having diametrically adjustable electrodes
AUTHOR: Laufer Michael D; Burger Keith M; Loomas Bryan E; **Tanaka Donald A** (Reprint
AUTHOR ADDRESS: San Jose, CA, USA**USA
JOURNAL: Official Gazette of the United States Patent and Trademark Office Patents 1250 (1): Sep. 4, 2001 2001
MEDIUM: e-file
PATENT NUMBER: US 6283989 PATENT DATE GRANTED: September 04, 2001 20010904
PATENT CLASSIFICATION: 607-96 PATENT ASSIGNEE: Broncus Technolgies, Inc., Mountain View, CA, USA PATENT COUNTRY: USA
ISSN: 0098-1133
DOCUMENT TYPE: Patent
RECORD TYPE: Abstract
LANGUAGE: English

...AUTHOR: **Tanaka Donald A**

ABSTRACT: A device and method for treating collapsed bronchial tubes found in patients with **chronic obstructive pulmonary** disease and asthma are provided. The device delivers energy so that the tissue is inductively...

4/3,K/6 (Item 4 from file: 5)
DIALOG(R)File 5:Biosis Previews(R)
(c) 2004 BIOSIS. All rts. reserv.

0013347004 BIOSIS NO.: 200100518843
Bronchial stenter having expandable electrodes
AUTHOR: Laufer Michael D; Burger Keith M (Reprint); Loomas Bryan E; **Tanaka Don A**
AUTHOR ADDRESS: San Francisco, CA, USA**USA
JOURNAL: Official Gazette of the United States Patent and Trademark Office Patents 1250 (1): Sep. 4, 2001 2001
MEDIUM: e-file
PATENT NUMBER: US 6283988 PATENT DATE GRANTED: September 04, 2001 20010904
PATENT CLASSIFICATION: 607-96 PATENT ASSIGNEE: Broncus Technologies, Inc.
PATENT COUNTRY: USA
ISSN: 0098-1133
DOCUMENT TYPE: Patent
RECORD TYPE: Abstract
LANGUAGE: English

...AUTHOR: **Tanaka Don A**

ABSTRACT: An apparatus and method are provided for treating collapsed bronchial tubes found in patients with **chronic obstructive pulmonary** diseases, such as asthma. The apparatus delivers energy to inductively heat the tissue of the...

4/3,K/7 (Item 5 from file: 5)
DIALOG(R)File 5:Biosis Previews(R)
(c) 2004 BIOSIS. All rts. reserv.

0012568301 BIOSIS NO.: 200000286614
Bronchial stenter having diametrically adjustable electrodes
AUTHOR: Laufer Michael D (Reprint); Burger Keith M; Loomas Bryan E; **Tanaka Donald A**
AUTHOR ADDRESS: San Jose, CA, USA**USA
JOURNAL: Official Gazette of the United States Patent and Trademark Office Patents 1227 (4): Oct. 26, 1999 1999
MEDIUM: e-file
PATENT NUMBER: US 5972026 PATENT DATE GRANTED: October 26, 1999 19991026
PATENT CLASSIFICATION: 607-96 PATENT ASSIGNEE: Broncus Technologies, Inc., Mountain View, CA, USA PATENT COUNTRY: USA
ISSN: 0098-1133
DOCUMENT TYPE: Patent
RECORD TYPE: Abstract
LANGUAGE: English

...AUTHOR: **Tanaka Donald A**

ABSTRACT: A device and method for treating collapsed bronchial tubes found in patients with **chronic obstructive pulmonary** disease and asthma are provided. The device delivers energy so that the tissue is inductively...

4/3,K/8 (Item 1 from file: 34)
DIALOG(R)File 34:SciSearch(R) Cited Ref Sci
(c) 2004 Inst for Sci Info. All rts. reserv.

00950260 Genuine Article#: FH323 No. References: 0
Title: THE COMPARATIVE VALUE OF THE HISTORY, PHYSICAL AND PEAK FLOW METER AT PREDICTING CHRONIC OBSTRUCTIVE PULMONARY -DISEASE
Author(s): BADGETT RG; **TANAKA DJ** ; PETTY TL
Corporate Source: UNIV COLORADO,HLTH SCI CTR,DIV GEN INTERNAL MED/DENVER//CO/80262; UNIV COLORADO,HLTH SCI CTR,DIV PULM MED/DENVER//CO/80262
Journal: CLINICAL RESEARCH, 1991, V39, N2, PA587
Language: ENGLISH Document Type: MEETING ABSTRACT

Title: THE COMPARATIVE VALUE OF THE HISTORY, PHYSICAL AND PEAK FLOW METER AT PREDICTING CHRONIC OBSTRUCTIVE PULMONARY -DISEASE
Author(s): BADGETT RG; **TANAKA DJ** ; PETTY TL

4/3,K/9 (Item 1 from file: 73)
DIALOG(R)File 73:EMBASE

10674894 EMBASE No: 2000159046
Letters to the editor [1] (multiple letters)
Badgett B.; **Tanaka D.** ; Sippel J.; Osborne M.
Dr. B. Badgett, Univ. of Texas Health Science Center, San Antonio, TX United States
Journal of General Internal Medicine (J. GEN. INTERN. MED.) (United States) 2000, 15/4 (273)
CODEN: JGIME ISSN: 0884-8734
DOCUMENT TYPE: Journal; Letter
LANGUAGE: ENGLISH

Badgett B.; **Tanaka D.** ; Sippel J.; Osborne M.
MEDICAL DESCRIPTORS:
medical literature; **chronic obstructive lung** disease--complication --co; **chronic obstructive lung** disease--diagnosis--di; **chronic obstructive lung** disease--epidemiology--ep; screening test; clinical research; health program; demography; letter

---

4/3,K/10 (Item 2 from file: 73)
DIALOG(R)File 73:EMBASE

05936491 EMBASE No: 1994348090
The clinical evaluation for diagnosing obstructive airways disease in high-risk patients
Badgett R.G.; **Tanaka D.J.** ; Hunt D.K.; Jelley M.J.; Feinberg L.E.; Steiner J.F.; Petty T.L.
Department of Medicine, UT HSC-SA, 7703 Floyd Curl Drive,San Antonio, TX 78284-7879 United States
Chest (CHEST) (United States) 1994, 106/5 (1427-1431)
CODEN: CHETB ISSN: 0012-3692
DOCUMENT TYPE: Journal; Article
LANGUAGE: ENGLISH SUMMARY LANGUAGE: ENGLISH

Badgett R.G.; **Tanaka D.J.** ; Hunt D.K.; Jelley M.J.; Feinberg L.E.; Steiner J.F.; Petty...
MEDICAL DESCRIPTORS:
* **chronic obstructive lung** disease--diagnosis--di; * **chronic obstructive lung** disease--drug therapy--dt

4/3,K/11 (Item 1 from file: 94)
DIALOG(R)File 94:JICST-EPlus

05230593 JICST ACCESSION NUMBER: 02A0430557 FILE SEGMENT: JICST-E
Changes of the physiological parameters of very low-birthweight infants with chronic lung disease treated with dexamethasone.
TAKEUCHI T (1); **TANAKA D** (1); SAIKAWA N (1); SATOH H (1); IWASAKI J (1); INOUE M (1); NARUI K (1); IIKURA Y (1)
(1) Showa Univ., Tokyo, Jpn
Pediatr Int, 2002, VOL.44,NO.2, PAGE.122-126, FIG.2, TBL.2, REF.19
JOURNAL NUMBER: Z0373BBO ISSN NO: 1328-8067
UNIVERSAL DECIMAL CLASSIFICATION: 616.2-085 618.1/.2-085:615.256 577.175.5
LANGUAGE: English COUNTRY OF PUBLICATION: Japan
DOCUMENT TYPE: Journal
ARTICLE TYPE: Original paper
MEDIA TYPE: Printed Publication

TAKEUCHI T (1); **TANAKA D** (1); SAIKAWA N (1); SATOH H (1); IWASAKI J (1); INOUE M (1); NARUI K (1); IIKURA Y...
(1)
...DESCRIPTORS: **oxygen** inhalation **therapy** ;

```
Set     Items   Description
S1        277   AU=(TANAKA D? OR TANAKA, D?)
S2      16833   OXYGEN(2N)THERAP? OR COPD OR CHRONIC()OBSTRUCT?()(LUNG? OR
             PULMON?)
S3          2   S1 AND S2
S4          2   RD (unique items)
? show files
File  16:Gale Group PROMT(R) 1990-2004/May 03
         (c) 2004 The Gale Group
File 160:Gale Group PROMT(R) 1972-1989
         (c) 1999 The Gale Group
File 148:Gale Group Trade & Industry DB 1976-2004/May 03
         (c)2004 The Gale Group
File 149:TGG Health&Wellness DB(SM) 1976-2004/Apr W4
         (c) 2004 The Gale Group
File 621:Gale Group New Prod.Annou.(R) 1985-2004/Apr 30
         (c) 2004 The Gale Group
File 444:New England Journal of Med. 1985-2004/May W1
         (c) 2004 Mass. Med. Soc.
File 441:ESPICOM Pharm&Med DEVICE NEWS 2004/Apr W4
         (c) 2004 ESPICOM Bus.Intell.
File 369:New Scientist 1994-2004/Apr W4
         (c) 2004 Reed Business Information Ltd.
File 370:Science 1996-1999/Jul W3
         (c) 1999 AAAS
File 129:PHIND(Archival) 1980-2004/Apr W4
         (c) 2004 PJB Publications, Ltd.
File 130:PHIND(Daily & Current) 2004/Apr 30
         (c) 2004 PJB Publications,Ltd.
File 135:NewsRx Weekly Reports 1995-2004/Apr W4
         (c) 2004 NewsRx
File  98:General Sci Abs/Full-Text 1984-2004/Apr
         (c) 2004 The HW Wilson Co.
File  15:ABI/Inform(R) 1971-2004/May 01
         (c) 2004 ProQuest Info&Learning
?
```

4/3,K/1 (Item 1 from file: 148)
DIALOG(R)File 148:Gale Group Trade & Industry DB
(c)2004 The Gale Group. All rts. reserv.

07944582 SUPPLIER NUMBER: 15012884 (USE FORMAT 7 OR 9 FOR FULL TEXT)
The diagnostic value of the forced expiratory time. (includes reply) (Letter to the Editor)
Kern, David G.; Patel, Sunit R.; Badgett, Robert; **Tanaka, David** ; Schapira, Ralph M.; Schapira, Marilyn M.; Funahashi, Akira; McAuliffe, Timothy L.; Varkey, Basil
JAMA, The Journal of the American Medical Association, v271, n1, p25(2)
Jan 5, 1994
DOCUMENT TYPE: Letter to the Editor ISSN: 0098-7484 LANGUAGE: ENGLISH RECORD TYPE: FULLTEXT
WORD COUNT: 1258 LINE COUNT: 00110

... **Tanaka, David**
... 1993;270:731-736.
2. Badgett RG, Tanaka DJ, Hunt DK, et al. Can moderate **chronic obstructive lung** disease be diagnosed by historical and physical findings alone? Am J Med. 1993;94: 88...

4/3,K/2 (Item 1 from file: 149)
DIALOG(R)File 149:TGG Health&Wellness DB(SM)
(c) 2004 The Gale Group. All rts. reserv.

01495898 SUPPLIER NUMBER: 15928006 (USE FORMAT 7 OR 9 FOR FULL TEXT)
The clinical evaluation for diagnosing obstructive airways disease in high-risk patients.
Badgett, Robert G.; **Tanaka, David J.** ; Hunt, Debra K.; Jelley, Martina J.; Feinberg, Lawrence E.; Steiner, John F.; Petty, Thomas L
Chest, v106, n5, p1427(5)
Nov,
1994
PUBLICATION FORMAT: Magazine/Journal ISSN: 0012-3692 LANGUAGE: English
RECORD TYPE: Fulltext TARGET AUDIENCE: Professional
WORD COUNT: 3416 LINE COUNT: 00296

... **Tanaka, David J**
... half of those referred for spirometry would have abnormal results. (Chest 1994; 106:1427-31)
COPD = **chronic obstructive pulmonary** disease; FET=forced expiratory time; [FEV.sub.1]=forced expiratory volume in 1 s; FVC...

...airways disease; peak flowmeter; physical diagnosis; recursive partitioning; screening; spirometry
Obstructive airways disease (OAD), including **chronic obstructive pulmonary** disease (**COPD**) and asthma, are common and morbid illnesses. **COPD** is the fifth most common cause of death and the second leading cause of disability in the United States.(1)(2) However, only 19 percent of patients with **COPD** in the Rand Health Insurance Study had had their conditions previously diagnosed by a physician...RG, Tanaka DJ, Hunt DK, Jelley MJ, Feinberg LE, Steiner JF, et al. Can moderate **chronic obstructive pulmonary** disease be diagnosed by historical and physical findings alone? Am J Med 1993; 94:188...

...M, Schindler D, Shapira J, Chen B. The 'ruler sign'--a semiquantitative physical sign of **chronic obstructive pulmonary** disease. Isr J Med Sci 1988; 24:10-2

(11)Schneider IC, Anderson AE. Correlation...Dis Chest 1969; 63:29-37
(31)Hepper NG, Hyatt RE, Fowler WS. Detection of **chronic obstructive lung** disease: an evaluation of the medical history and physical examination. Arch Environ Health 1969; 19...

```
Set      Items   Description
S1        4944   COPD OR CHRONIC?()OBSTRUCT?()(PULMON? OR LUNG?) OR HYPOXIA?
             OR HYPOXEM? OR HYPOXAEM? OR CRICOTHRYO?
S2      353629   OXYGEN OR 02
S3        1824   (CHEST OR THORAC? OR THORAX?)(3N)WALL? ? OR TRANS()THORA? -
             OR TRANSTHORA? OR INTRATHORA? OR INTRA()THORA? OR TRANSTRACH?
             OR INTRATRACH? OR (INTRA OR TRANS)()TRACH?
S4      162674   THERAPY? OR THERAPI? OR THERAPEUT? OR (FORCED OR COLLATERA-
             L?)()(VENTILAT? OR OXYGENAT?) OR SUPPLEMENT?
S5     1680685   CONDUIT? ? OR HOSE? ? OR STENT? ? OR PIPE? ? OR TUBE? ? OR
             CATHETER? OR CANNULA? OR IT02C
S6     1565075   SUBCUTAN? OR IMPLANT? OR EMPLANT? OR EMPLAC? OR IMPLAC? OR
             INSERT? OR INTUBAT? OR PUNCTUR? OR INVASIVE? OR INVIVO OR VIVO
             OR PIERC? OR PENETRAT? OR PERFORAT?
S7      801011   SEAL OR SEALS OR SEALED OR SEALING OR SEALANT OR GROMMET? -
             OR GASKET? OR (FIBRIN OR BIOCOMPATIBL?)()(GLUE? ? OR ADHESIVE?
             ?) OR (BALLOON OR FIXED)()FLANGE? ?
S8      776504   VALVE? ? OR VALVING
S9     4064259   METHOD? ?
S10    2974336   SYSTEM? ?
S11    2407724   PROCESS??
S12     197825   PROCEDURE? ?
S13     221126   TECHNIQUE? ?
S14      94384   IC=A61M?
S15          1   S1 AND S2 AND S3 AND S4 AND S5 AND S6
S16          6   S1 AND S2 AND S4 AND S5 AND S6
S17          6   S16 AND S7:S14
S18          1   S1 AND S2 AND S3 AND S5 AND S6
S19        148   S9:S13 AND S1 AND S2 AND S4
S20      15155   CHEST? ? OR THORAC? OR THORAX?
S21          2   S19 AND S20
S22         59   S19 AND S5:S7
S23          1   S22 AND S20
S24          8   S15:S18 OR S21 OR S23
S25          8   IDPAT (sorted in duplicate/non-duplicate order)
? show files
File 347:JAPIO Nov 1976-2003/Dec(Updated 040402)
         (c) 2004 JPO & JAPIO
File 350:Derwent WPIX 1963-2004/UD,UM &UP=200427
         (c) 2004  Thomson Derwent
?
```

APPLICATION

25/3,K/2 (Item 2 from file: 350)
DIALOG(R)File 350:Derwent WPIX

016000773 **Image available**
WPI Acc No: 2004-158623/200416
XRAM Acc No: C04-063267
XRPX Acc No: N04-126751
Long-term oxygen therapy system **for treating** hypoxemic **patients having** chronic obstructive pulmonary **disease, includes** oxygen **supply, valve,** conduit **, and** sealing **device that provides fluid tight** seal **between** conduit **and** thoracic **wall**
Patent Assignee: CORDIS CORP (CRDC); TANAKA D (TANA-I)
Inventor: TANAKA D
Number of Countries: 033 Number of Patents: 003
Patent Family:

Patent No	Kind	Date	Applicat No	Kind	Date	Week
EP 1386635	A1	20040204	EP 2003254748	A	20030729	200416 B
CA 2436483	A1	20040131	CA 2436483	A	20030731	200416
US 20040024356	A1	20040205	US 2002399907	P	20020731	200416
			US 2003613358	A	20030703	

Priority Applications (No Type Date): US 2003613358 A 20030703; US 2002399907 P 20020731
Patent Details:

Patent No	Kind	Lan	Pg	Main IPC	Filing Notes
EP 1386635	A1	E	13	A61M-037/00	
CA 2436483	A1	E		A61M-016/00	
US 20040024356	A1			A61M-029/00	Provisional application US 2002399907

Designated States (Regional): AL AT BE BG CH CY CZ DE DK EE ES FI FR GB GR HU IE IT LI LT LU LV MC MK NL PT RO SE SI SK TR

Long-term oxygen therapy system **for treating** hypoxemic **patients having** chronic obstructive pulmonary **disease, includes** oxygen **supply, valve,** conduit **, and** sealing **device that provides fluid tight** seal **between** conduit **and** thoracic **wall**

Abstract (Basic):
... A long-term **oxygen therapy system** (100) has an **oxygen** supply (102); valve (106); **conduit** (s) (104) having a first end connected to the **oxygen** supply and a second end passing through the **thoracic** wall and lung (108) of a patient to establish fluid communication between the **oxygen** supply and the inner volume of the lung; and a **sealing** device connected to the **conduit** (s) and providing a fluid tight **seal** between the **conduit** (s) and the **thoracic** wall.
... For the treatment of **hypoxemic** patients having **chronic obstructive pulmonary** disease (claimed), e.g. emphysema or chronic bronchitis...

...The inventive long-term **oxygen therapy system** improves **oxygen** transfer efficiency in the lungs to reduce **oxygen** supply requirements, which in turn reduces the patient's medical costs. It also allows for...

...The figure is a diagrammatic view of a long term **oxygen therapy system** of the invention...

...Long term **oxygen therapy system** (100...

... **Oxygen** supply (102...

... **Conduit** (104
...Title Terms: **OXYGEN** ;

25/3,K/8 (Item 8 from file: 350)
DIALOG(R)File 350:Derwent WPIX

004652414
WPI Acc No: 1986-155757/198624
XRAM Acc No: C86-066610
XRPX Acc No: N86-115752
Catheter **for** transtracheal **indwelling** oxygen supplementing **- has constant dia. bore, reinforcement and forwardly and downwardly directed outlets**
Patent Assignee: SPOFFORD B T (SPOF-I); TP INT CORP (TPIT-N)
Inventor: CHRISTOPHER K L; SPOFFORD B T
Number of Countries: 016 Number of Patents: 007
Patent Family:

Patent No	Kind	Date	Applicat No	Kind	Date	Week	
WO 8603127	A	19860605	WO 85US2282	A	19851119	198624	B
EP 207099	A	19870107	EP 85906119	A	19851119	198701	
JP 62502168	W	19870827	JP 85505374	A	19851119	198740	
CA 1267343	A	19900403				199018	
EP 207099	B	19910724				199130	
DE 3583611	G	19910829				199136	
US 5181509	A	19930126	US 85883409	A	19851119	199307	
			US 91784123	A	19911029		

Priority Applications (No Type Date): US 85788817 A 19851018; US 84673912 A 19841121
Patent Details:

Patent No	Kind	Lan	Pg	Main IPC	Filing Notes
WO 8603127	A	E	54		
Designated States (National): JP KR SU US					
Designated States (Regional): AT BE CH DE FR GB IT LU NL SE					
EP 207099	A	E			
Designated States (Regional): AT BE CH DE FR GB IT LI LU NL SE					
EP 207099	B				
Designated States (Regional): AT BE CH DE FR GB IT LI LU NL SE					
US 5181509	A		18	A61M-016/00	Cont of application US 85883409

Catheter **for** transtracheal **indwelling** oxygen supplementing -

...Abstract (Basic): **Catheter** for patients with **chronic obstructive pulmonary** disease comprises a flexible **tube** with durometer hardness of 80-90 to have its distal end within the tracea above the carina. The **tube** has a smooth cylindrical outer surface and constant i.d. of 1.7-2.5...

...The **tube** has reinforcement to maintain constant lumen cross-section and has a hydrophilic coating on at...

...distal end internal and external surfaces to limit adhesion and build-up of mucous. The **tube** has a distal end downwardly facing outlet opening of the same dia. as the **tube** bore, and further openings through the sidewall above the end opening and directing **oxygen** towards the anterior part of the trachea only...

...ADVANTAGE - Limits rearward flow of **oxygen** to prevent mucosal damage. (54pp Wg.No.0/22)

...Abstract (Equivalent): A **system** for providing a continuous **supplementary** supply of **oxygen** , so as to enhance spontaneous breathing of a patient having chronic **hypoxaemia** , comprising an elongated **transtracheal catheter** (T,C) in the form of a **tube** (10)

having an external portion (58,68) with an **oxygen** inlet at is free end, a **subcutaneous** portion (54) having **oxygen** outlet means (12,78) in a distal end portion (70) thereof, for insertion through an incision into the patient's trachea, and a locating abutment (18) fixed externally...

...external abutment on the patient's skin at the incision, characterised in that: (a) the **tube** (10) is a continuous, flexible, deformation-resistant **tube** of constant diameter having a continuous lumen (60,76) of constant diameter therethrough; (b) the **oxygen** inlet is a coupling (24) for releasable connection to a **tube** (26) for the said supply of **oxygen** at low pressure and at a relatively low flow rate; (c) the coupling (24) is spaced away from the abutment (18) by a substantial length of the **tube** (10), so that it can be seen and manipulated by the patient when the **c**atheter is being worn; and (d) the **subcutaneous** portion (54) includes an intermediate portion extending from the abutment (18) to its distal end...

...a curved shape in an upper part of the trachea while permitting free flow of **oxygen** between the inlet (24) and outlet means (12,78). (23pp)

...Abstract (Equivalent): Appts. supplying **oxygen** to **supplement** ventilation without interfering with normal breathing comprises a **transtracheal catheter** with a flexible **tube** having a proximal end **oxygen** supply connector (24) and an i.d. of 1.7-2.5 mm. and o.d. less than that of the trachea. **Tube** length is sufficient to extend from outside the patient to above and adjacent to the carina. The **tube** has a distal outlet (80) and a wall for flexible introduction while resisting deformation. The **tube** wall pref. has a Shore A durometer value of 80-90 and a hydrophilic coating...

...USE/ADVANTAGE - Esp. used in **chronic obstructive pulmonary** disease and may be installed on a semi-permanent out-patient basis for efficient long-term **oxygen therapy** . (Dwg.1/22)

Title Terms: **CATHETER** ;

International Patent Class (Main): **A61M-016/00**

```
Set       Items   Description
S1         9515   COPD OR CHRONIC?()OBSTRUCT?()(PULMON? OR LUNG?) OR HYPOXIA?
            OR HYPOXEM? OR HYPOXAEM? OR CRICOTHRYO?
S2       364158   OXYGEN OR 02
S3         5988   (CHEST OR THORAC? OR THORAX?)(3N)WALL? ? OR TRANS()THORA? -
            OR TRANSTHORA? OR INTRATHORA? OR INTRA()THORA? OR TRANSTRACH?
            OR INTRATRACH? OR (INTRA OR TRANS)()TRACH?
S4        24108   CHEST? ? OR THORAC? OR THORAX?
S5       428159   THERAPY? OR THERAPI? OR THERAPEUT? OR (FORCED OR COLLATERA-
            L?)()(VENTILAT? OR OXYGENAT?) OR SUPPLEMENT?
S6       516074   CONDUIT? ? OR HOSE? ? OR STENT? ? OR PIPE? ? OR TUBE? ? OR
            CATHETER? OR CANNULA? OR IT02C
S7       708799   SUBCUTAN? OR IMPLANT? OR EMPLANT? OR EMPLAC? OR IMPLAC? OR
            INSERT? OR INTUBAT? OR PUNCTUR? OR INVASIVE? OR INVIVO OR VIVO
            OR PIERC? OR PENETRAT? OR PERFORAT?
S8       308212   SEAL OR SEALS OR SEALED OR SEALING OR SEALANT OR GROMMET? -
            OR GASKET? OR (FIBRIN OR BIOCOMPATIBL?)()(GLUE? ? OR ADHESIVE?
            ?) OR (BALLOON OR FIXED)()FLANGE? ?
S9        194016   VALVE? ? OR VALVING
S10      1300633   METHOD? ?
S11      1136491   SYSTEM? ?
S12      1011052   PROCESS??
S13       443912   PROCEDURE? ?
S14       572019   TECHNIQUE? ?
S15        32556   IC=A61M?
S16         1773   S1 AND S2 AND S3:S4 AND S5 AND S6 AND S7
S17         1153   S16 AND S8:S9
S18         1773   S16 AND S10:S14
S19           93   S16 AND S15
S20           93   S17:S18 AND S19
S21         1773   S16:S20
S22          288   S21 AND S2(5N)S5
S23           40   S22 AND S7(5N)S3:S4
S24           25   S23 AND S8:S9
S25           40   S23:S24
S26           40   IDPAT (sorted in duplicate/non-duplicate order)
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File 348:EUROPEAN PATENTS 1978-2004/Apr W04
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File 349:PCT FULLTEXT 1979-2002/UB=20040415,UT=20040408
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26/3,K/1 (Item 1 from file: 348)
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TRANSTRACHEAL CATHETER SYSTEM.
TRANSTRACHEALES **KATHETERSYSTEM.**
SYSTEME **DE** CATHETER TRANSTRACHEAL .
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TRANSTRACHEALES **KATHETERSYSTEM.**
SYSTEME **DE** CATHETER TRANSTRACHEAL .
INTERNATIONAL PATENT CLASS: **A61M-016/00**
LEGAL STATUS (Type, Pub Date, Kind, Text):
...Drawing up of a **supplementary** European search report...

...SPECIFICATION B1
This invention pertains to a **system** for supplemental **transtracheal** **oxygen** **therapy** including **transtracheal** **catheter** devices for providing **transtracheal** , **oxygen** delivery for spontaneously breathing patients with chronic lung disease and to **methods** for **catheter** placement and use. Such devices are medically desirable **therapy** for patients having a chronic need for **oxygen** where a **catheter** can be installed on an out-patient basis for permanent use.
As a result of...

...the 1960's and early 1970's, it has been determined that long-term continuous **oxygen** **therapy** is beneficial in the treatment of **hypoxemic** patients with **chronic** obstructive **pulmonary** disease (**COPD**

). In other words, a patient's life and quality of life can be improved by providing a constant **supplemental** supply of **oxygen** to the patient's lungs.

However, with the current desire to contain medical costs, there is a growing concern that the additional cost of providing continuous **oxygen therapy** for chronic lung disease will create an excessive increase in the annual cost of **oxygen therapy** . Thus, it now desirable that **oxygen therapy** , when provided, be as cost effective as possible.

The standard treatment for patients requiring **supplemental oxygen** is still to deliver **oxygen** from an **oxygen** source by means of a nasal **cannula** . Such treatment, however, requires a large amount of **oxygen** , which is wasteful and can cause soreness and irritation to the nose, as well as...

...Various other medical approaches which have been proposed to help reduce the cost of continuous **oxygen therapy** have been studied.

Various devices and **meth**ods have been devised for performing emergency cricothyroidotomies and for providing a tracheotomy **tube** so that a patient whose airway is otherwise blocked may continue to breath. Such devices...

...for the long term treatment of chronic lung disease. Typically, such devices are installed by **puncturing** the skin to create a hole into the cricoid membrane of the larynx above the trachea into which a relatively large curved tracheotomy **tube** is **inserted** . As previously described, the use of such **tubes** has been restricted medically to emergency situations where the patient would otherwise suffocate due to the blockage of the airway. Such emergency tracheotomy **tubes** are not suitable for long term **therapy** after the airway blockage is removed.

Other devices which have been found satisfactory for emergency...

...Weiss, et al.; and U.S. Patent No. 3,916,903 to Pozzi.

Although tracheotomy **tubes** are satisfactory for their intended purpose, they are not intended for chronic usage by outpatients as a means for delivering **supplemental oxygen** to spontaneously breathing patients with **chronic** obstructive **pulmonary** disease (**COPD**). Such tracheotomy **tubes** are generally designed so as to provide the total air supply to the patient for a relatively short period of time. The tracheotomy **tubes** are generally of rigid or semi-rigid construction and of caliber ranging from 2.5 mm outside diameter in infants to 15 mm outside diameter in adults. They are normally **inserted** in an operating room as a surgical **procedure** or during emergency situations, through the crico-thyroid membrane where the tissue is less vascular...

...both directions until normal breathing has been restored by other means.

Another type of tracheotomy **tube** is disclosed in Jacobs, U.S. Patent No. 3,682,166 and U.S. Patent No. 3,788,,326. The **catheter** described therein is placed over 14 or 16 gauge needle and **inserted** through the crico-thyroid membrane for supplying air or **oxygen** and vacuum on an emergency basis to restore the breathing of a con-breathing patient. The air or **oxygen** is supplied at 30 to 100 psi for inflation and deflation of the patient's lungs. The Jacobs **catheter** , like the other tracheotomy **tubes** previously used, is not suitable for long term outpatient use, and could not easily be adapted to such use.

Due to the limited functionality of tracheotomy **tubes** , **transtracheal catheters** have been proposed and used for long term **supplemental oxygen therapy** . For example the small diameter **transtracheal catheter** (16 gauge) developed by Dr. Henry J. Heimlich (described in THE ANNALS OF OTOLOGY, RHINOLOGY & LARYNGOLOGY, Nov.-Dec. 1982;

Respiratory Rehabilitation with **Transtracheal Oxygen System**) has been used by the **insertion** of a relatively large cutting needle (14 gauge) into the trachea at the mid-point between the crico-thyroid membrane and the sternal notch. This **catheter** size can supply **oxygen** up to about 3 liters per minute at low pressures, such as 2 psi which...

...use and maintenance, such as periodic removal and cleaning, primarily because the connector between the **catheter** and the **oxygen** supply **hose** is adjacent and against the anterior portion of the trachea and cannot be easily seen and manipulated by the patient. Furthermore, the **catheter** is not provided with positive means to protect against kinking or collapsing which would prevent...home care use. Also, because of its structure, i.e. only one exit opening, the **oxygen** from the **catheter** is directed straight down the trachea toward the bifrucation between the bronchi. Because of the...

...at a more acute angle to the trachea than the right bronchus, more of the **oxygen** from that **catheter** tends to be directed into the right bronchus rather an being directed or mixed for more equal utilization by both bronchi. Also, as structured, the **oxygen** can strike the carina, resulting in an undesirable tickling sensation and cough. In addition, in such devices, if a substantial portion of the **oxygen** is directed against the back wall of the trachea causing erosion of the mucosa in...

...cause of the limited output from the device, it may not operate to supply sufficient **supplemental oxygen** when the patient is exercising or otherwise quite active or has severe disease.

Thus, none...

...long term basis.

It is therefore an objective of the present invention to provide a **transtracheal catheter system** which will provide for efficient long term **oxygen therapy** , particularly for active patients.

We acknowledge the earlier disclosure, in WO86/03127, by the present inventors, of a **transtracheal catheter system** having **oxygen** supply means for continuously supplying **oxygen** to a patient to **supplement** normal spontaneous atmospheric breathing; flexible **oxygen** supply **tube** means for supplying **oxygen** from said **oxygen** supply means to the patient; a continuous one-piece constant diameter flexible elongated **intratracheal tube** means connected to said **oxygen** supply **tube** means and having a continuous constant diameter passage, a straight distal side wall portion and an unrestricted distal end outlet opening, said **intratracheal tube** means having an outside diameter so as to be substantially less in area than the...

...enabling normal breathing and having an inside diameter such as to enable free flow of **oxygen** therethrough from said inlet opening to said outlet opening;

said outlet opening on said distal end portion of said **intratracheal tube** means having an inclined end surface, and defining a longitudinally extending slot means in said...

...only the front of the trachea of the patient for enabling only forward flow of **oxygen** without rearward flow toward the rear trachea surface;

and a support and locating means mounted on an exterior proximate end portion of said **intratracheal tube** means for supporting said **intratracheal tube** means at an operative position; said support and locating means being mounted for abutting association with the skin of the patient circumjacent said **intratracheal tube** means; and

an external **oxygen** supply **tube** means connected to the proximate end portion of said **intratracheal tube** means for supplying **oxygen**

from said **oxygen** supply means.

The present invention provides an apparatus for supplying **supplemental oxygen** to a patient as defined in Claims 1 and 9. The **oxygen** is preferably from a portable supply of **oxygen** which is capable of being carried by such patient, and which **oxygen** is capable of being introduced uniformly into both of the lungs of such patient on a continuous long term daily basis by conduction of **supplemental oxygen** into the cervical trachea (below the cricoid and above the sternal notch) through the **transtracheal tube** .

In one form of the invention, the **transtracheal tube** means unit comprises one continuous length of tubing, and in another presently preferred form comprises a separate **intratracheal catheter** member and a separate external **oxygen** supply **tube** member. In the preferred embodiment, the **intratracheal catheter** apparatus comprises an elongated flexible **tube** means having a durometer of from about 70 to about 90 Shore A and a...

...end portion outwardly of the neck for attachment of the proximate end portion to a **tube** connected to a portable supply of **oxygen** carried by the person; the **intratracheal tube** means having a lumen having a continuous smooth cylindrical outer peripheral surface and a continuous ...

...polymeric material having an inside diameter of between 1.7 and 3.0 millimeters; and **oxygen** outlet opening means at the distal end portion of the tubular means including a downwardly and anteriorly facing oval end opening, when said **tube** means is in place in the trachea, formed by a beveled end surface. The distal end portion of said **tube** means may also additionally contain a plurality of side wall openings located in predetermined spaced...

...said sidewall and facing generally forwardly toward the anterior portion of the trachea for supplying **oxygen** only in a forwardly facing direction whereby rearward flow of **oxygen** toward the posterior portion of the trachea is limited to prevent erosion. The **tube** means may additionally contain reinforcement means mounted completely within said sidewall between said outer peripheral...

...end portion and said sidewall openings for maintaining a constant lumen cross-section in said **tube** means by resisting restriction of said central passage means in order to maintain said continuous constant diameter of said central passage means during **oxygen therapy** use. In the presently preferred form of the invention, the reinforcement means is located in the external **oxygen** supply **tube** member. The **tube** means may also be provided with hydrophilic ...of mucous-type materials present in the trachea which would otherwise restrict the flow of **oxygen** through said **tube** means. Thus the **intratracheal catheter** , as previously described, comprises a thin, flexible, kink and collapse resistant, tracheal **tube** means having a proximate end and a distal end which is fixedly attached to a flanged support means engageable with the patient neck and connected to an external **oxygen** supply **tube** means which may be an exterior portion of one continuous length of tubing or a separate outwardly extending **tube** member. A releasable connector means is attached to the outwardly extending proximate end of the external **tube** portion a sufficient distance so as to be capable of being viewed by the patient, so that the patient is better able to connect the external **tube** portion to a source of **oxygen** and to facilitate cleaning the **catheter** on an out-patient basis.

A **method** of **inserting** a **transtracheal catheter** in the trachea

of a patient comprises, under local anaesthesia, the steps of infiltrating the...

...the anaesthetised tissue into the trachea; injecting local anaesthetic into the trachea through the needle; **inserting** a guide wire through the needle; removing the needle over the guide wire; **inserting** a tissue dilator over the guide wire to enlarge the tract; removing the dilator; **inserting** a **Stent** over the guide wire and through the enlarged tract; removing the guide wire; securing the **Stent** by appropriate means, in place for a first period of time while initial healing of...

...sterno rather than accumulating under the skin with the adherent risk of injury; removing the **Stent** ; **inserting** a first **catheter** in the tract, which may be used on a temporary or longer-term basis, and securing the first **catheter** in place until the tract completely heals. Then, the first **catheter** may be removed and a second **catheter** may be **inserted** . This unique **method** allows the use of a small needle for the **insertion** of a **catheter** which is larger than the needle, but still capable of providing sufficient supplemental oxygen for **oxygen therapy** with active patients and not so large as to require a major surgical operation to **insert** . The first **catheter** is designed to enable cleaning in place by a cleaning rod with saline solution. The second **catheter** is designed to enable cleaning by removal by the patient.

The preferred apparatus for carrying out the foregoing **procedure** to create the tract can be provided in the form of a first kit. The...

...use with a syringe for injecting an anesthetic into the trachea after the needle is **inserted** through the trachea to form the tract. The first kit also includes a guide wire for **insertion** through the needle to maintain the tract after the needle is removed. A dilator is...

...to gradually stretch the tissue to increase the diameter of the tract or opening. A **Stent** , having a central passageway is also provided in the kit and is **inserted** in the dilated tract after the dilator is removed in order to maintain the size...

...opening to facilitate initial healing of the tract. The guide wire is then removed. The **Stent** is held in position during healing by suturing.

A second kit or package includes the first **catheter** which has a single opening at a beveled distal end and replaces the **Stent** . The beveled end on the first **catheter** is longer on the posterior side so that the **oxygen** stream is directed away from the mucosa and toward the center of the trachea. This first **catheter** remains in place until the healing is complete and can be connected to a supply of oxygen during this period. A cleaning rod is also included in the second kit which is used periodically to clean out mucous which may form in the distal end of the **catheter** . To facilitate disconnecting and reconnecting the **oxygen** supply and the cleaning of the **catheter** , the proximate end of the **catheter** extends a sufficient distance outwardly from the surface of the tissue and the **catheter** holder so that the patient can see the connector thereon over his chin. Finally, a third kit or package includes a removable, second **catheter** which has similar dimensions as the first **catheter** and replaces the first **catheter** at the end of the tract healing period. The second **catheter** has a tapered distal end like the temporary **catheter** and also has a series of spaced openings in the anterior side wall thereof to facilitate mixing of the **oxygen** supplied through the **tube** with the air inhaled by the patient. These openings are spaced about an arc which...

...not exceed 60(sup(o) from the mid-line on the anterior side of the **tube** .

The kits which have been described, together with the unique first and second **catheters** , provide the means for installing the **catheters** by a unique **method** . The **catheters** are suitable for out-patient use over extended periods of time by patients suffering from lung diseases causing **hypoxia** . The **catheters** can be cleaned by the patients, the second **catheter** being removable by the patient for cleaning and reinsertion. Because of the external extension of the proximate end of the **tube** beyond the connecting flange of the disclosed fastening means, the patient can see the connector and easily manipulate it to connect and disconnect the **oxygen** and instill drugs or other ...taken in conjunction with the accompanying drawings.

Fig. 1 is a perspective view showing the **transtracheal catheter** of this invention mounted through the skin and into the trachea of a patient and showing the **oxygen** supply connecting **tube** secured to the patient's wearing apparel between the connection to the **transtracheal catheter** and the connector to a supply of **oxygen** ;

Fig. 2 is a diagrammatical illustration of the infiltration of a local anesthetic into the...

...means of a needle on a syringe;

Fig. 3 is a diagrammatical illustration of the **insertion** of a guide wire through the needle after the syringe is removed;

Fig. 4 is a diagrammatical illustration of the **insertion** of a tissue dilator over the guide wire after the needle is removed;

Fig. 5 is a diagrammatical illustration of the **insertion** of the **Stent** after the dilator and the guide wire have been removed;

Fig. 6 is a diagrammatical illustration of the **insertion** of a first **transtracheal catheter** after removal of the **Stent** ;

Fig. 7 is a diagrammatical illustration of the **insertion** of a second **catheter** , after removal of the first **catheter** ;

Fig. 8 is a diagrammatic view of the trachea with a flush-mounted prior art **catheter** showing the orientation of the **catheter** and the flow of **oxygen** to the patient from the **catheter** ;

Fig. 9 is a diagrammatic view of the trachea, similar to Fig. 8, but showing the thorough mixing of **oxygen** and air by means of the **catheter** of this invention;

Fig. 10 is a side elevation of guide wire which forms a...

...which forms a part of the first kit of this invention, for use in the **method** of **implanting** the **transtracheal catheter** of this invention;

Fig. 12 is an end view of the distal end of the dilator of Fig. 11;

Fig. 13 is a side elevation of a **Stent** which forms a part of the first kit of this invention;

Fig. 14 is a...

...a second kit of this invention;

Fig. 15 is a side elevation of a first **catheter** which forms a part of the second kit of this invention;

Fig. 16 is a side elevation of a removable, second **catheter** which forms a part of this invention;

Fig. 17 is an enlarged vertical section, taken...

...section, taken along line 19-19 of Fig. 16 showing an attachment means for the **transtracheal catheter** ;

Fig. 20 is a graph comparing **oxygen therapy** by an analysis of blood **oxygen** during exercise of the **catheter** of the present invention

compared to other **therapies** ;

Fig. 21 is a perspective view of a presently preferred embodiment of the **system** , including a **transtracheal** unit and an **oxygen** supply **hose** unit in use with a patient;

Fig. 22 is a longitudinal cross-sectional view of the **transtracheal** unit shown in Fig. 1 prior to **insertion** into the trachea;

Fig. 23 is a transverse cross-sectional view of the **transtracheal** unit of Fig. 22 taken along line 23-23;

Fig. 24 is an enlarged longitudinal cross-sectional view of the external reinforced **tube** member of the **transtracheal** unit of Fig. 22;

Fig. 25 is a side elevational view partly in cross-section of a **Stent** ;

Fig. 26 is an end view of the **Stent** of Fig. 25;

Fig. 27 is a longitudinal cross-sectional view of the connector member of the **transtracheal** unit of Fig. 22;

Fig. 28 is an end view of the connector member of Fig. 27;

Fig. 29 is a longitudinal side elevational view of the **oxygen** tank connector member for the **oxygen** supply **hose** unit shown in Fig. 1;

Fig. 30 is a longitudinal cross-sectional view of the connection member of Fig. 29;

Fig. 31 is a side elevational view of the **transtracheal** unit connector member for the **oxygen** supply **hose** unit of Fig. 1; and

Figs. 32 & 33 show a cleaning rod.

As best seen in Fig. 1, a patient P has been fitted with a **transtracheal catheter** C. In one form of the invention, the **catheter** includes a flexible **tube** 10 having a beveled distal end opening and may have a plurality of side wall...

...the distal end thereof which hava a specific orientation to facilitate the mixing of the **oxygen** with the air being breathed by the patient, as more fully explained hereinafter. The distal...

...a tract in the trachea 14, is positioned above the carina 15 to supply the **oxygen** to the right and left bronchus 16 and 17. The **catheter** is **inserted** into the cervical trachea, in a manner more fully described hereinafter. After **insertion** , attachment means 18 is used to secure the **catheter** C to the patient's neck by means of a chain 20 extending around the patient's neck.

The proximate end of **catheter** C extends away from the patient's body and has a connector 24 attached to **tube** 10 through which **oxygen** is supplied to the patient. As is readily apparent, the extension provided, makes it possible...

...patient to see connector 24 over his chin so as to connect and disconnect the **oxygen** supply **tube** and to even remove the **catheter** , as an outpatient, at home, for cleaning and then replace it and reconnect the **oxygen** supply. The source of **oxygen** can be from any source of **oxygen** such as pressurized **oxygen** tanks, liquid **oxygen** reservoirs or **oxy**gen concentrators, with some variation in the prescribed flow rates.

As shown in Fig. 1, an intermediate reinforced **tube** 26 is provided which is connected between connector 24 through clip 30 which in shown...

...30 can be attached directly to the patient's wearing apparel instead of using a **supplemental** belt. The connector 34 is then connected to **tube** 36 to **oxygen** supply 38. The purpose of this structure is to assure that as the patient moves...

...patient will not move to the limit of the tubing and place a stress on

catheter C which could pull the **catheter** out of the trachea and perhaps cause injury or discomfort to the patient. With the intermediate tubing arrangement as shown, any tension would be placed on **tube** 36 and not on **tube** 26. In addition, the connector 24 is designed to disengage this also when subjected to a 4.5-13.2 N (1 -.3 pound) pull.

The **catheter system** of the present invention may include two **catheters** . The first is sometimes referred to herein as a temporary **catheter** which is used for a limited period of time while the tract or fistula formed through the trachea heals. The second **catheter** is sometimes referred to as the final **catheter** which is capable of being used by the patient on a long term basis but...

...home, for cleaning on a periodic basis. However, it will be understood that the first **catheter** may also be used on a long-term basis without use of the second **catheter** . The differences in these **catheters** will be more fully explained hereinafter. Both **catheters** are made of the same material and, with some differences, have the same dimensions. In this regard, for an adult patient, the **catheter** will have a length of approximately 20 cm and be made of polyurethane having a...

...breathing of the patient. The attachment means 18 is located near the midpoint of the **tube** after placement and is approximately 7 to 11 cm (preferably 9 cm) from connector 24 on the proximate end of the **tube** and approximately 9 to 13 cm (preferably 11 cm) from the distal end of the **tube** when in place in the trachea. For an adult, the preferred diameter is an 8 or 9 French **catheter** . In some instances, it is contemplated that the outside diameter might be as small as...

...Of course, the length would be correspondingly shorter to prevent the problems previously discussed.

The **method** of **inserting transtracheal catheter** C is best illustrated in Figs. 2-7. Conveniently, the **method** can be carried out by using apparatus contained in three kits. The first kit contains a hypodermic needle, a guide wire, a dilator and a **Stent** . The second kit contains the temporary **catheter** and a cleaning rod. A final **catheter** and a cleaning rod are contained in the third hit. In Fig. 2, a local...

...of the needle, the possibility of hemorrhaging is greatly reduced even though the tissue being **penetrated** is vascular. A 32 cm straight guide wire 42 is passed through the 18 gauge...

...the trachea as seen in Fig. 3. The bevel on the needle and angle of **insertion** are exploited to direct the guide wire downwardly into the trachea. Conveniently, indicia, such as...

...designed not to scratch or otherwise injure the mucosa or trachea when the wire is **inserted** . This atraumatic end is preferably about 5 cm long. The wire includes a central longitudinal...

...at about 11 cm from the atraumatic end to advise the physician on depth of **insertion** .

Next, preferably a 10 French by 15 cm long Teflon dilator D, found in the...

...small tract or fistula created by the hypodermic needle 40 is generally enlarged by the **insertion** of the taper of distal end 45 of the dilator into the tract. As the dilator is **inserted** no further than mark 48, see Fig. 11, the tract is stretched without cutting until it is enlarged sufficiently to receive the **Stent** . The tapered ...the tissue.

Next the dilator is removed with the wire remaining in place and the

Stent S is passed through the tract into the trachea over the wire, as best seen in Fig. 5. The structure of **Stent** S is illustrated in Figs. 13.

The flange serves to stabilize the **Stent** by sutures placed through its eyelets and adapts to conventional Luer taper connectors for installation of lidocaine to suppress coughing. The **Stent** has a body 51 which is made of sufficiently rigid material to hold the tract which has been formed in the trachea open. This **Stent** body 51 has, preferably, a 9 French diameter and is preferably about 11 cm long...

...the distal tapered end 52 to the proximal end 50. The tapered end 52 facilitates **insertion** of **Stent** S through the tract in the trachea. A passageway 53 extends through the **Stent** to allow air to pass out without going under the skin to minimize the danger of the patient experiencing **subcutaneous** emphysema, during the **process** .

After typically one week, or longer if indicated, **Stent** S is removed by the physician and a temporary **catheter** T is **inserted** , as shown in Fig. 6. One form of structure of this **catheter** is best seen by reference to Fig. 16. The temporary **catheter** is longer than the **Stent** , being about 20 cm in length. In fact, the length of the distal end 54 temporary **catheter** T which rests inside the trachea is approximately 11 cm long, which is the same length as the distal end of the **Stent** . The temporary **catheter** has a connector 56 at the proximate end 58 thereof for attachment to an **oxygen** supply. The extra length provided by proximate end 58 makes it possible for the patient to see connector 56 so that he can easily connect or disconnect the **oxygen** supply and can clean the **catheter** , as described below. This form of the **catheter** also has a longitudinal passageway 60 extending its entire length and may be provided with...

...within the tubular material that forms proximate end 58 and distal end 54 of temporary **catheter** T. The purpose of this armoring is to reduce the possibility of the **catheter** collapsing, or kinking from any manipulation done by the patient to thereby help assure a constant supply of **oxygen** to the patient by keeping a constant cross-sectional area in the **catheter** lumen. This is important since this device will be used by an outpatient who will...

...portion 54 has a taper 62 which is longer on the posterior side to facilitate **insertion** and also to deflect the **oxygen** introduced through the **cath**eter away from the mucosa at the back of the throat and to direct the **oxygen** downwardly and slightly forwardly. After proper positioning the temporary **catheter** T is connected to a source of **oxygen** . The **oxygen** flow is then adjusted to achieve a blood **oxygen** saturation of at least 90% by ear oximetry or arterial blood gas analysis.

Since **oxygen** is now being supplied to the patient through temporary **catheter** T, it is necessary to keep passageway or lumen 60 open. This is accomplished by...

...the shaft 64. Shaft 64 is slightly longer than the total length of the temporary **catheter** T. To clean out the **catheter** , the **oxygen** is disconnected and a saline solution is instilled through the passage, and then shaft 64 of cleaning rod R is **inserted** through connector 56 and along passageway 60. Because of the sizing, the length of shaft...

...After cleaning, the cleaning rod R is removed and the connector 56 is reconnected to **oxygen** supply.

The temporary **catheter** is preferably kept in place for six weeks or longer so that the tract or...

...the trachea can heal completely. After complete healing has occurred, the physician removes the temporary **catheter** T and provides the patient with a final **catheter** C which is **inserted** and positioned as shown in Fig. 7. This **catheter** is similar to the temporary **catheter** T with certain differences, as enumerated below.

The structure of one embodiment of the final **transtracheal catheter** C, which is a part of the third kit, is shown in Figs. 16-19. The upper or proximate portion 68 of the **catheter tube** 10, as well as the lower portion 70, is also reinforced by means such as...

...this armoring is also intended to reduce the possibility of collapse or kinking of the **transtracheal catheter** which could restrict the **oxygen** supply to the patient. Conveniently, coil spring 72 extends a sufficient distance along the length of **tube** 10 to provide the described features with flange or fastening means 18 located at about...

...an aperture 74 (Fig. 19) for receiving a chain 20, or other holding means. The **catheter tube** 10 is provided with a longitudinal passageway or lumen 76 and the distal end has a taper 78 with a longer posterior side for directing the **oxygen** away from the mucosa of the trachea. A plurality of openings 12 are spaced about the anterior side of the **catheter** through an arc of approximately 120(sup(o) and are all positioned on the portion...

...o) to either side of a mid-line 80 on the anterior side of the **tube** 10, as shown in Fig. 18.

The distinct advantage of this arrangement will be apparent from a viewing of Figs. 8 and 9. In Fig. 8, a prior art **catheter** K is shown having a tubular body member 82 with a flat distal end 84 and no openings in the sidewall. As can be seen, most of the **oxygen** is directed straight downwardly in a stream into the right main stream bronchus 16 since...

...shown by arrows 86, will be less likely to effectively mix with the stream of **oxygen** from the distal end 84 of **catheter** K as shown by arrows 88.

On the other hand, in one embodiment shown in Fig. 9, **oxygen** is discharged from **catheter** C through the beveled or tapered distal end 78 and openings 12 so as to...

...the patient's natural breathing, as indicated by arrows 92. This will occur because the **oxygen** is issued in multi-directional streams so that a substantial equal amount of **oxygen** enriched air passes essentially uniformly into both the right bronchus 16 and the left bronchus 17 and minimizes the drying effect of **oxygen** on the mucous membranes.

Another important distinction between the prior art **catheter** K and **catheter** C is that the connector of **catheter** K is flush against the trachea whereas the proximate end or extension 68 of **catheter** C extends outwardly for about 9 cm. This makes **catheter** C suitable for outpatient use, whereas **catheter** K is not. With extension 68, the patient can see connector 24 over his chin so that he can connect and disconnect the **oxygen** supply easily and can periodically remove the **catheter** for cleaning.

Oxygen is delivered at very low pressures, such as below 1.4 x 10(sup 4...

...flow rates, which are usually 50% or less than that which is required with a **cannula** . Of course, the **catheter** is only for use by a spontaneously breathing outpatient. Individuals who require more than 3 liters per minute **transtracheal catheter** either at rest or during

exercise can receive up to 6 - 8 l/min. with the **catheter** of the present inventions. It can be seen from this chart that with the same flow rates in liters per minute for the 16 gauge **catheter** and the **catheter** of the present invention, blood oxygenation is improved for the described device. The nasal **cannulae** is clearly not as effective as the **transtracheal catheters** of the present invention even if operated at higher flow rates. Thus, a substantial savings can be obtained from reduced **oxygen** use while providing active patients with better blood gas values during the **therapy** . Used on a long term basis, this difference in efficiency should produce even more advantages...

...of useful life.

From the foregoing, the advantages of this invention are readily apparent. A **transtracheal catheter** has been provided which is safe and comfortable for a spontaneously breathing patient and can be installed in a doctor's office on an outpatient basis without requiring hospitalization. A **method** of installation is provided whereby the **transtracheal catheter** is **inserted** under a local anesthetic, with the patient remaining ambulatory all times. Because of its small size, **insertion** can be accomplished with no risk of severing an artery. The **transtracheal catheter** is armored so that the possibility of kinking and crushing is minimized to assure a continuous supply of **oxygen** to the patient. Disconnection and reconnection of the **oxygen** supply is facilitated. The constant flow of low pressure **oxygen** into the collapsed airways of emphysema patients helps hold the bronchial **tubes** open to improve the function of the lungs and reduce the work of breathing.

The...

...is constructed as described, with biocompatible materials where necessary. For example, the temporary and permanent **catheters** are preferably constructed as described from medical grade polyurethane which may be coated as described...

...in use, to tracheal secretions. The polymer also provides a lubricious surface for ease of **insertion** and removal. The polymer, also minimizes adherence of mucus to the **catheter** . Such polymers are currently used on other commercially available medical products such as feeding **tubes** which are in contact with mucosal surfaces for prolonged periods. The PVC material used in...

...polyurethane can be securely bonded together.

The bevel of the tip of temporary and permanent **catheters** , and the side ports of the permanent **catheter** direct **oxygen** away from the tracheal mucosa toward the center of the air column in the trachea...type taper connector is a feature which will result in a safety disconnect rather than **catheter** dislodgement in the event of an excessive pull on the proximal end of the **Oxygen Hose** .

The Cleaning Rod is designed to remove debris as it is passed through the lumen of either the temporary or permanent **catheter** . The length is preferably 5mm longer than the **catheter** , and over- **insertion** or loss down the **catheter** is prevented by the 2cm handle which is at a 90(sup(o) angle and the small cap at the end of the handle.

Both, the temporary and permanent **catheter** of the present invention is most preferably an 8 or 9 French reinforced **tube** made of medical grade clear polyurethane with nylon coil spring reinforcement and approximately 20cm (7.875") in length.

The kink and crush resistant **Oxygen Hose** adapts standard **oxygen** sources to the **cat**heter . Inadvertent decannulation is protected against

by the suspender-type security clip which attaches to the...

...and the 9 N (2 pound) safety release of the Luer taper connector between the **hose** and the **catheter** .

In summary, the durometer values, i.e. about 70-90 Shore A, selected for the final configurations of the temporary and permanent **catheters** of the present invention are desirable and indeed necessary for proper **insertion** and long term patient comfort. In this regard, the spacing for the location of the holes of the distal end of the permanent **catheter** are preselected, within the range of orientation described, to retain a sufficient flexibility and stiffness to facilitate proper **insertion** , removal and cleaning, as well as enabling proper orientation, when in place, in order to...

...the benefits described herein. An 8 or 9 French size of the temporary and permanent **catheter**s is the most preferred size since tests have shown that the proper back pressure, for a preselected range of **oxygen** flow rates can be achieved for this size of **catheter** to permit the efficient utilization of **supplemental** **oxygen** described herein.

In a presently preferred form of the invention, as shown in Figs. 21 - 31, a **transtracheal** **catheter** unit 100 comprises an **intratracheal** **tube** means 102, an external **oxygen** supply **tube** means 104, a connector-stabilizer-support means 106 with a releasable **oxygen** **hose** connector means 108. An **oxygen** supply **hose** unit 110 comprises a **tube** member 111, a non-releasable connector means 112, a clip means 113, a **tube** member 114, a connector means 115 fixedly attached to **tube** member 111 and a releasable coupling means 116 fixedly attached to **tube** member 114 which is releasably connectable to an **oxygen** supply source 118; such as a relatively small-size, small-volume (e.g. 0.6 to 1.1 liters of liquid **oxygen**) lightweight patient portable supply tank 117 capable of supplying 1/2 liter of gaseous **oxygen** for 10 to 12 hours through conventional **valve** flow control means or a relatively large-size, large-volume (e.g. 30 liters of liquid **oxygen**), heavy, stand alone-type, main supply cylinder or the like (not shown). Supply tank 117 ...

...118 having a shoulder or back strap 119.

As shown in Figs. 22 - 24, the **intra**tracheal tube means 102 comprises a continuous one-piece tubular member having an annular passage 120 defined...

...upwardly spaced portion 129. Tip portion 128 is preferably molded and polished for ease of **insertion** , comfort and avoidance of mucosal irritation. A plurality of forwardly facing side discharge openings 130 ...

...133 has a flat transverse end surface 133 defining a cylindrical inlet opening 134.

The **intratracheal** **tube** means 102 comprises a continuous, one-piece, tubular member made from a length of straight...

...thermoplastic tubular material such as polyurethane which easily conforms to the human anatomy to enable **insertion** into the trachea and has thermosetting characteristics so as to be able to adopt a...

...subject to body temperature in continuous use in the trachea. Thus, a portion of the **intratracheal** **tube** member will gently rest against the posterior trachea wall in a stable position and will...

...walls with normal respiratory excursions while still maintaining a balance of overall flexibility for comfort. **Intratracheal** **tube** member

102 has a durometer of between 70 to 90 Shore A (80 Shore A being presently preferred). **Tube** member 102 has an outside diameter of between 1.8 millimeters to 3.5 millimeters...

...e.g. 1.5 to 2.7 mm) for pediatric patients. The inside diameter of **tube** member 102 is between 1.7 to 3.0 mm (1.9 mm being presently...

...between 0.1 to 0.9 mm (0.6mm being presently preferred). The length of **tube** member 102 for adults is between approximately 8cm to 14 cm (11 cm being presently...Flat inner surface 141 provides an abutment surface to engage the neck skin about the **insertion** tract. An upper flat peripheral surface 143 is connected by relatively large radius curved side...

...72 inch)) as the inside diameter (e.g. 1.85 cm (0.73 inch)) of **tube** member 102, is located in a transverse flange portion 154 between counterbores 155, 156 which...

...tapered and have diameters approximately equal to or slightly less than the outside diameters of **tube** members 102, 104 so as to enable slidable, low-friction **insertion** of the ends of the **tube** members therewithin into abutting engagement with the side surfaces of flange portion 154. The end portions of the **tube** members 102, 104 are fixedly sealably attached to member 106 by any suitable means such...

...applying a suitable solvent material to the outer periphery of each tubular portion prior to **insertion** into the counterbores. While it is intended that both **tube** members 102, 104 be permanently connected to member 106, the construction and arrangement is such...

...forces (e.g. 36 to 67,5 N (8 to 15 pounds)), the bond between **tube** 104 and member 106 will break before the flange breaks away from the security necklace. **Tube** member 102 is precisely oriented relative to flange portion 140 so that the **oxygen** discharge opening in the tip portion 128 and side wall **oxygen** passages 130 will be properly located in the trachea whereby the **oxygen** is discharged forwardly. Flange portion 140 stabilizes the **tube** member 102, has a low profile and small surface area and is made of soft material for comfort and non-irritation in use while allowing the skin around the **insertion** tract in the neck to breathe. Flange portion 140 has circular openings 157, 158 for receiving a neck chain or band member 158 as previously described.

External **tube** means 104 is made of kink and crush-resistant molded plastic material such as polyurethane...

...or polypropylene which resists cracking and breaking. Preferably, clear plastic material is used for cosmetics. **Tube** means 104 has a length of approximately between 2 to 12 cm (8 cm being...

...distance beyond the connector-stabilizer-support member 106 to enable movement without displacement of the **intratracheal** **tube** member 102 and for comfort and ease of cleaning. **Tube** means 104 has a central cylindrical smooth-wall constant diameter passage 160 in an annular...

...diameter of passage 160 is approximately the same as the diameter of passage 120 in **tube** member 102 and passage 153 in flange portion 154 of member 106. In the presently preferred embodiment, **tube** member 104 has a durometer of approximately 80 Shore A, an outside diameter of approximately...

...27 & 28, is of the same general construction as a conventional Luer

compatible tapered **oxygen** friction connector device and is made of a one piece, generally cylindrical member 170 made...

...175, 176. Counterbore 173 has a diameter approximately equal to the outside diameter of external **tube** member 104 and has a slightly outwardly tapered surface 177 so as to enable **tube** end portion 166 to be slidably **inserted** into engagement with annular side surface 178 of rib portion 171 and then permanently connected...

...191, a central abutment flange portion 192, and a ribbed end portion 193 for fixed **insertion** into the end of **tube** member 111. In this manner, the elongated tapered connecting male portion 191 of connecting means 115 on the end portion of tubular member 111 is **insertable** into passage 174 of connector means 108 and securely releasably held therein with a retention...

...and liquid capsules, to apply liquid medications or the like.

In the present preferred embodiment, **oxygen** supply **tube** member 111 is ...approximately 3 mm (1/8 inch) and a length of approximately 51 cm (20 inches). **Oxygen** supply **tube** member 114 is made of extruded plastic material, such as PVC having a durometer of...

...of approximately 3 mm (1/8 inch) and length of about 130 cm (50 inches). **Tube** members 111, 114 are permanently connected by connector member 112 by solvent bonding in aligned counterbores as previously described. **Tube** members 111,114 preferably have the same inside diameters to prevent back pressure variances and...

...with a plastic loop member 113L fixedly secured thereto and slidably adjustable frictionally mounted on **tube** member 114 adjacent connector 112 for attachment to a belt of any size.

Oxygen tank connector means 116, Figs. 29 and 30, comprises an elongated body member of molded...

...presently preferred), which is integrally fixedly molded around and bonded to end portion 114E of **tube** member 114 which terminates at 114T in abutting engagement with rib portion 194 adjacent a...

...in rib portion 194 and having a diameter approximately equal to the inside diameter of **tube** member 114. Head portion 196 has a cylindrical end portion 202 and an annular, outer...

...is adapted to releasably receive an elongated ribbed male coupling portion 210, Fig. 21, on **oxygen** tank 117. The construction and arrangement of connector means 116 is such as to provide...

...enable the user to firmly grip the connector means during connection and disconnection from the **oxygen** supply means without kinking of **tube** member 114. The tapered passage 195 facilitates connection to the **oxygen** supply **hose** and provides a reduced diameter transition to the supply **hose** inlet opening to minimize back pressure. The enlarged head portion prevents breakage and cracking of the wall portion.

Figs. 25 & 26 shows a 9 French **Stent** device 220 which is generally similar to **catheter** unit portions 102 and 106 and comprises a one piece tubular member 221 having a...

...bonding as previously described. Counterbore portion 231 has a size and tapered shape to enable **insertion** of a standard size syringe. Relatively small-size openings 234, 236 in flange portion 225...

...are smaller than the chain diameter to prevent use of the support chain 159 with **Stent** support member 224.

A presently preferred **catheter** cleaning rod 240, shown in Figs. 32 & 33, comprises an 0.5 mm (0...

...head portion 244 having an outside diameter approximately equal to the inside diameter of the **tube** . An injection molded plastic handle member 246, fixedly mounted on the other end of the wire, comprises a flat abutment surface 248 to prevent over- **insertion** of the wire beyond the tip of the **catheter** ; a pair of flat side surfaces 250, 251 with indentations 252, 253 for gripping; and a rounded side surface 254.

Thus, the presently preferred embodiment of the invention provides a **transtracheal catheter** unit 100 having **oxygen** flow capability of from 0.1 to 8 liters per minute through an **intratracheal tube** member having an inside diameter of 1.7 to 3.0 millimeters. The **intratracheal tube** member is made of flexible thermoplastic material having a durometer of 70 to 90 Shore...

...is variable for each individual patient while enabling usage of a cleaning rod within the **oxygen** passage in the **intratracheal tube** member. The construction and arrangement is such that the **catheter** tip rests against the smooth posterior wall portion of the trachea so as to reduce...the trachea. The outside diameter is sufficiently small to permit unrestricted spontaneous breathing around the **catheter** . The **catheter** tip is beveled and positively oriented by the external connecting-locating flange so that the long axis of the oval opening faces forwardly to direct **oxygen** away from the tracheal mucosa to protect against drying and irritation. When relatively high flow rate **oxygen** (e.g. 2 to 8 liters per minute) is to be used, the side holes located near the tip portion further disperse the **oxygen** in a forward direction for comfort and to minimize drying. The **oxygen** passage is open to enable usage of a cleaning rod. The **oxygen** supply **hoses** and connector members provide for safety and ease of usage. The **catheter** - **oxygen** supply **hose** connector member provides a 4.5 to 22 N (1 to 5 pound force) safety disconnect feature. The stabilizer member is connected to the **tube** members in a manner providing an 33,6 to 63 N (8 to 14 pound) force safety separation feature. The large connector member at the end of the supply **hose** means provides an impedance matching feature while also being kink and crush resistant. The inside diameters of all **tube** members and passages in connecting members are approximately the same so as to provide a continuous substantially unrestricted constant passage between the tip portion of the **intratracheal catheter** and the source of **oxygen** .

In summary, the invention comprises a **system** for providing a continuous **supplemental** supply of relatively low pressure **oxygen** at a relatively low flow rate to enhance spontaneous breathing of a person having chronic **hypoxemia** . The **system** comprises an elongated **intratracheal tube** means having an elongated continuous constant diameter central passage means extending between an **oxygen** inlet opening means at a proximate end portion of the **intratracheal tube** means and an **oxygen** outlet opening means at a distal end portion thereof. The **intratracheal tube** means is fixedly permanently mounted on an external connector-stabilizer-support means for mounting on and support by the neck of a person and **insertion** into the trachea of the person through a surgically formed permanent **insertion** opening in the skin of the person located in the cervical trachea of the person. The external connector-stabilizer-mounting means is oriented relative to the **intratracheal tube** means for locating the distal end portion and the **oxygen** outlet opening means in the trachea below the cricoid cartilage

and in upwardly spaced relationship...

...support means and has a length such as to provide a proximate end portion and **oxygen** inlet opening means located a sufficient distance away from the **insertion** opening in the skin to enable flexible displacement relative to the connector-stabilizer-support means without causing displacement of the **intratracheal** tubular means. The **intratracheal** tubular means is made of a continuous one-piece constant diameter flexible elongated intatracheal **tube** member having a continuous constant diameter passage extending therethrough and having thermosetting characteristics being flexible when **inserted** into the functional position within the trachea to provide therein an intermediate curved side wall...

...having an unrestricted distal end outlet opening located in upwardly spaced relationship to the bronchial **tubes** of the patient. The **intratracheal tube** member has a relatively small outside diameter of between 1.8 to 3.5 mm...

...90 Shore A such as to prevent collapse, kinking or other deformation causing restriction of **oxygen** flow and to enable continuous free flow of relatively low pressure relatively low flow rate **oxygen** therethrough from the inlet opening to the outlet opening with the pressure of the **oxygen** being no more than 1.4 x 10(sup 4) Nm(sup -)(sup 2) (2...

...larynx and the sternum and for holding the connector-stabilizer-support means proximate to the **insertion** opening in the skin. A frictional coupling means is provided on a proximate end portion of the external **tube** means for releasable connection to an **oxygen** supply **tube** means which comprises a first portion for mounting next adjacent the upper body of the...

...beneath clothing and having a disconnectable coupling means for releasable frictional coupling to the external **tube** means. The **oxygen** supply **tube** means further comprises a second portion with a coupling means for coupling to the oxygen supply source.

The distal end outlet opening on the **intratracheal tube** member has an inclined end surface and defines a longitudinally extending oval opening or slot...

...side of the trachea of the patient for enabling only downward and forward flow of **oxygen** from the outlet opening and side facing slot means without rearward flow toward the rear side of the trachea.

A plurality of transverse laterally spaced forwardly facing **oxygen** outlet passage means may be provided in the distal side wall portion in upwardly spaced...of no more than 180(degree) circumference for enabling only forward and downward flow of **oxygen** toward the front of the trachea through the air outlet passage means without rearward flow...

...CLAIMS and

a locating abutment means (106) on said transtracheal tube means (100) for locating said **transtracheal** tube means relative to the **insertion** opening in the skin by abutting engagement with the skin circumjacent the **insertion** opening in the skin and for separating said **transtracheal tube** means into an elongated **subcutaneous** tubular means portion (102), including said distal end portion, located on one side of said locating abutment means for mounting in the trachea and for further separating said **transtracheal tube** means into an external tubular means portion (104), including said proximate end portion, for connection to an **oxygen** supply (118);

characterised by:

the external tubular means portion (104) having a length between said locating abutment means and said proximate end portion such as to space said **oxygen** inlet opening means a sufficient distance away from the **insertion** opening in the skin to enable flexible displacement relative to said attachment abutment means without causing displacement of said **subcutaneous** tubular means portion (102);

said **subcutaneous** tubular means portion (102) being made of a continuous one-piece constant diameter flexible elongated **intratracheal tube** member with thermosetting characteristics having a continuous constant diameter passage extending therethrough and being flexible when **inserted** into an operative position within the trachea to provide therein an intermediate, thermoset, curved side...

...having an unrestricted distal end outlet opening located in upwardly spaced relationship to the bronchial **tubes** (16,17) of the person;

said **intratracheal tube** member having an outside diameter, of between 1.8 and 3.5 mm or 1...

...durometer between 70 and 90 Shore A, such as to prevent deformation causing restriction of **oxygen** flow and to enable continuous free flow of the **oxygen** therethrough from said inlet opening to said outlet opening, the pressure of the **oxygen** being no more than 1.4 x 10(sup 4) Nm(sup -)(sup 2) (2 psi) and the flow rate of the **oxygen** being no more than 8 liters per minute; and

said locating abutment means including neck...

...to said locating abutment means and for holding said locating abutment means proximate to the **insertion** opening in the skin. ...

...CLAIMS B1

26/3,K/4 (Item 4 from file: 349)
DIALOG(R)File 349:PCT FULLTEXT

00130618 **Image available**
TRANSTRACHEAL CATHETER SYSTEM **AND** METHOD
CATHETER TRANSTRACHEAL **ET PROCEDE D'INSTALLATION**
Patent Applicant/Assignee:
T P INTERNATIONAL CORPORATION,
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TRANSTRACHEAL CATHETER SYSTEM **AND** METHOD
CATHETER TRANSTRACHEAL **ET PROCEDE D'INSTALLATION**
Main International Patent Class: **A61M-016/00**
Fulltext Availability:
Detailed Description
Claims

English Abstract
...42, D, S, T, R, C) containing apparatus for use in the placement of specific **transtracheal catheters** (40, D, S, T) for varying periods, including a **transtracheal catheter** (C) suitable for in-dwelling long-term **oxygen supplementation therapy** for patients with **chronic obstructive pulmonary** disease, by its size, **perforation** location and cleanability, and a **method** for placement.

French Abstract
...40, 41, 42, D, S, T, R, C) contenant un dispositif utilise pour placer des **catheters transtracheaux** specifiques (40, D, S, T) pour des periodes variables, comprenant un **catheter transtracheal** (C) indique pour l'installation a demeure, grace a sa taille, l' **emplacement** de la **perforation** et les possibilites de nettoyage, afin de soumettre des patients presentant des troubles pulmonaires obstructifs chroniques a une **therapie** d'oxygenation **supplementaire** de longue duree. Un procede d'installation du **catheter** est egalement decrit.

Detailed Description
TRANSTRACHEAL CATHETER SYSTEM AND **METHOD**
Background of the Invention
Technical Field.

This invention pertains to a **system** for **supplemental transtracheal oxygen therapy** including **trans tracheal catheter** devices for providing **transtracheal oxygen** to spontaneously breathing patients with chronic lung disease and to **methods** for **catheter** placement and use, Such devices are medically desirable **therapy** for patients having a chronic need for **oxygen** where a **catheter** can be installed on a semi-permanent out patient basis.

As a result of studies...

...in the 1960's
and early 19701s, it has been determined that long-term continuous **oxygen therapy** is beneficial in the treatment of **hypoxemic** patients with **chronic obstructive pulmonary** disease (**COPD**) In other words,, a patient's quality and length of life can be improved by providing a constant **supplemental** supply of **oxygen** to the patient's lungs.

However, with the current desire to contain medical costs, there is a growing concern that the additional cost of providing continuous **oxygen therapy** for chronic lung disease will create an excessive increase in the cost of **oxygen therapy** . Thus, it now desirable that oxyge n **therapy** , when provided, be as cost effective as possible.

The standard treatment for patients requiring **supplemental oxygen** is still to deliver **oxygen** from an **oxygen** source by means of a nasal **cannula** . Such treatment, however, requires a large amount of **oxygen** , which is wasteful and can cause soreness and irritation to 'the nose,, as well as...

...reported.

other medical approaches which have been proposed to help reduce the cost of continuous **oxygen therapy** have been studied.

Various devices and **methods** have been devised for performing emergency cricothyroidotomies and for providing a tracheotomy **tube** so that a patient whose airway is otherwise blocked may continue to breathe. is Such...

...a patient who is not breathing spontaneously and are not intended for the long-term **oxygen supplementation therapy** for chronic lung disease. Typically, such devices are installed by **puncturing** the skin to create a hole through the cricoid thyroid membrane above the trachea through which a relatively large curved trach eotomy **tube** is **inserted** . As previously described, the use of such **tubes** has been restricted medically to emergency situations where the patient would otherwise suffocate due to the blockage of the airway. Such emergency tracheotomy **tubes** are not intended for long-term **oxygen supplementation** therapy after the airway blockage is removed.
Other devices which have been found satisfactory for emergency...Weiss, et al.;
and U,S. Patent No. 3,916,903 to Pozzi.

Although tracheotomy **tubes** are satisfactory for their intended purpose, they are not intended for chronic usage by outpatients as a means for delivering **supplemental oxygen** to spontaneously breathing patients

with **COPD** . Such tracheotomy **tubes** are generally designed so as to provide the total air supply to the patient for a relatively short period of time. The tracheotomy **tubes** are generally of rigid or semi-rigid construction and of large caliber ranging from 2...

...mm
outside diameter in infants to 15 mm outside diameter in adults. The are normally **inserted** in an operating y I
room as a surgical **procedure** or in the emergency room during emergency situations, through the cricothyroid membrane where the tissue...
...directions
until nofmal breathing. ha@ been restored by other means.

A@other type of tracheotomy **tube** is disclosed in Jacobs, U.S, Patent No. 3,682,166 and U,S. Patent No.

31788jr326, The **catheter** described therein is placed over 14 or 16 gauge needle and **inserted** through the cricothyroid membrane for supplying air or **oxygen** and vacuum an an emergency basis to restore the breathing of a non-breathing patient, Because of resistance to gas flow created by the small inside diameter of the **tube** , the air or **oxygen** is supplied at very high pressures, i.e. from 30 to 100 psi for inflation and deflation of the patient's lungs. The Jacobs **catheter** , like the other tracheotomy **tubes** previously used, is not intended for long-term outpatient use, and could not easily be adapted to such use,
Due to the limited functionality of tracheotomy **tubes** , **transtracheal catheters** have been proposed and used for long-term **supplemental oxygen therapy** , For example the small diameter **transtracheal catheter** (16 gauge) developed by Dr. Henry J, Heimlich (described in THE ANNALS OF OTOLOGY, RHINOLOGY & LARYNGOLOGY, Nov.-Dec. 1982; Respiratory Rehabilitation with **Trans tracheal oxygen System**) has been used by the **insertion** of a relatively large cutting needle (14 gauge) into the trachea at the mid-point between the cricothyroid membrane and the sternal notch. This **catheter** size can supply **oxygen** up to about 2 to 3 liters per minute at low pressures, such as 2 psi, however this flow rate may be insufficient for patients who have higher **oxygen** requirements. It does not,, however, lend itself to convenient outpatient use and maintenance, such as periodic removal and cleaning, primarily because the connector between the **catheter** and the **oxygen** supply **hose** is ad-4acent and against the anterior portion of J.
the trachea and cannot be easily seen and manipulated by the patient, Furthermore, the- **catheter** is not provided with positive means to protect against kinking or collapsing which would prevent...home care use, Also, because of its structure,, i,e.
only one exit opening, the **oxygen** from the **catheter** is directed straight down the trachea toward the bifruca tion between the bronchi. Because of...

...at
a more acute angle to the trachea than the right bronchus, more of the **oxygen** from that **catheter** tends to be directed into the right bronchus rather than being directed or mixed for more equal utilization by both bronchi. Also, as structured, the **oxygen** can strike the mucous membrane of the carina, resulting in an undesirable sensation and a tendency to cough, In addition, in such devices, if a substantial portion of the **oxygen** is directed against the back wall of the trachea it may result in erosion of...

...because of
the limited output from the device, it may not operate to supply sufficient **oxygen** during **supplemental oxygen therapy** when the patient is exercising or otherwise quite active or has severe disease.
Thus, none...

...long-term basis.

it is therefore an objective of the present invention to provide a **catheter** , **catheter insertion system** and **method** for **catheter insertion** and use which will provide for efficient long-term **oxygen therapy** , particularly for active patients and severely ill patients with high **oxygen** requirements at rest.

Disclosure of the Invention
The present invention provides an apparatus for supplying **supp**lemental oxygen to a patient from a portable supply of **oxygen** which is capable of being carried-by such patient, and which **oxygen** is capable of being introduced uniformly into both of the lungs of such patient on a continuous long-term daily basis by conduction of **supplemental oxygen** into the cervical trachea (below the cricoid and above the sternal notch) through a **catheter** disposed in the trachea in a down wardly extending position in the trachea with a distal end portion of such **catheter** , structured and located in the lower trachea to promote adequate mixing of the **oxygen** introduced with the air from a normally breathing patient, the **catheter** apparatus comprising an elongated flexible **tube** means having a durometer of from about 80 to about 90 and a length sufficient...

...end
portion outwardly of the neck for attachment of the proximate end portion to a **tube** connected to a portable supply of **oxygen** carried by the person; the **tube** means of said **catheter** having a lumen having a continuous smooth cylindrical outer peripheral surface and a continuous smooth...

...lexible grade material having an inside diameter of between 1.7 and 2.5 millimeters; **oxygen** outlet opening means at ...a downwardly and generally anteriorly facing end opening of the same diameter as said continuous **oxygen** passage means when said **tube** means is in place

in the trachea, and said distal end portion of said **tube** means additionally containing a plurality of openings located in predetermined spaced relationship above said end...

...sidewall and facing generally forwardly toward the center of the tracheal air column for supplying **oxygen** only in a forwardly f acing direction whereby rearward f low of **oxygen** toward the posterior portion of the 4
trachea is limited to prevent erosion of the mucous membranes, said **tube** means additionally containing reinforcement means mounted either completely within said sidewall between said outer peripheral...

...or externally of the
tub.e for maintaining a constant lumen cross-section in said **tube** means by resisting restriction of said central passage means in preselected locations in order to maintain said continuous constant diameter of said central passage means during **oxygen** **therapy** use; said **tube** means also preferably being provided with hydro philic coating means on the portion which resides...
...mucous-type mater als present in
the trachea which would otherwise restrict the flow of **oxygen** through said **tube** means.

In addition, the present invention include's a kit for installing a **transtracheal** **catheter** for use in supplying **oxygen** on a substantially, low pressure basis directly to the bronchi of a spontaneously breathing outpatient for long-term treatment of chronic obstruc tion pulmonary disease. In a preferred form, the **catheter** , as previously described, comprises a thin, flexible, kink and collapse resistant, tracheal **tube** having a proximate end and a distal end, Preferably, reinforcement means such as a coil of wire or other reinforcing material is molded in the **tube** .

Alternatively, reinforcing means can be around the outer diameter of the external part of the **catheter** . A plurality of openings are also provided on the anterior side of the distal **tube** to facilitate mixing of the **oxy**gen with the air being breathed in by the patient. The openings are laterally spaced about a mid-line along the anterior side of the wall of the **catheter** through an arc of about 1201, i.e., up to about 60' on either side of the midline. A connector is attached to the outwardly extending proximate end of the **tube** a suffiAent distance so as'to be capable of being viewed by the patient so that the patient is better able to connect the **catheter** to a source of **oxygen** . Stabilizing means are provided so as to enable the patient to reduce the inadvertent movement of the **catheter** when it is in place and in use. With this arrangement, the proximate portion of the **catheter** extends out from the patient ...end
thereof can be viewed by the patient to facilitate his connecting and disconnecting the **oxygen** supply and to facilitate cleaning the **catheter** on an outpatient

basis, if necessary. The distal end is tapered with the posterior side being longer than the anterior side so as to direct **oxygen** away from the posterior wall against which it gently rests,
The invention also contemplates a **method** of **inserting** a **transtracheal catheter** in the trachea of a patient, The **method** comprises, under local anesthesia, the steps of infiltrating the soft tissue overlying the anterior side...

...the anesthesized tissue into the trachea; injecting local anesthetic into the trachea through the needle; **inserting** a guide wire through the needle; removing the needle over the guide wire; **inserting** a tissue dilator over the guide wire to enlarge the tract; removing the dilator; **inserting** a **stent** over the guide wire and through the enlarged tract; removing the guide wire; securing the **stent** by appropriate means, in place for a first period of time while initial healing of...

...occurs so as to allow air to freely pass out through the lumen of the **stent** during coughing, rather than accumulating under the skin with the adherent risk of injury; removing the **stent** ; **inserting** a temporary **catheter** in the tract; securing the temporary **catheter** in place for a,second longer period of time until the tract'completely matures; removing the temporary **catheter** ; **inserting** a removable fin-al **catheter** and releasably securing the final **catheter** in place. This unique **method** allows the use of a small needle f or the **insertion** of a **catheter** which is larger than the needle, and capable of provid ing sufficient **supplemental oxygen** for **oxygen therapy** with active patients but not so large as to require an operation to **insert** .

The preferred apparatus for carrying out the foregoing **method** can be provided in the form of a first kit, The **transtracheal catheter** described hereinbefore is one piece of the apparatus contained in the second kits The first...

...use with a syringe for injecting an anesthetic into the trachea after the needle is **inserted** through the trachea to form the tract. The first kit also includes a guide wire for **insertion** through the needle to maintain the tract after the needle is removed. The guide wire is marked at 11 cm. to prevent over- **inserting** . A dilator is also provided, which is tapered and has a central passageway for threading...

...of the tract or opening, The dilator is marked at 7 cm. to prevent over **insertion** . The dilator is then removed while keeping the guide wire in place, A **stent** , having a central passageway is also provided in the kit and is **inserted** in the dilated tract after the dilator is removed in order to maintain the size...

...opening to facilitate initial healing of the tract, The guide wire is then removed, The lstent is held in position during healing by suturing.

The second kit includes a **catheter** which has a single opening at a beveled distal end. and replaces the **stent** , The beveled end on the temporary **catheter** is longer on th7e posterior or superior side so that the **oxygen** stream is directed away from the mucosa and toward the center of the trachea. The temporary **catheter** can be connected to a supply of **oxygen** during this period and remains in place until healing is complete. A cleaning rod is...

...to clean out mucous plugs which may form in the distal end of the temporary **catheter** . To facilitate disconnecting and reconnecting the **oxygen** supply and the cleaning of the **catheter** ,. the proximate end of the **catheter** extends a sufficient distance outwardly from the surface of the neck and the stabilizing flange on the **catheter** so that the patient can see the connector thereon over his chin. Finally, the third kit includes a removable, final **catheter** which has the same dimensions as the temporary **catheter** and replaces the temporary **catheter** at the end of the tract healing period. The final **catheter** has a tapered distal end like the temporary **catheter** and also has a series of spaced openings in the anterior side wall thereof to facilitate mixing of the **oxygen** supplied through the **tube** with the air inhaled by the patient. These openings are spaced about an arc which does not exceed 601 from the midline on the anterior side of the **tube** .
The kits which have been described, together with the unique temporary and f inal **catheters** , provide the means for installing the **catheters** by a unique **method** , The **catheters** are suitable for outpatient use over extended periods of time by patients suffering from **COPD** , The **catheters** can be cleaned by the patients,, the final **catheter** being removable by the patient for cleaning and reinsertion. Because of the external extension of the proximate end of the **tube** beyond the connecting flange of the disclosed fastening means, the patient can see the connector and easily manipulate it to connect and disconnect the **oxygen** ,
-Additional advantages of the invention will become apparent from the description which follows, taken in...

...accompanying drawings.

Brief Description of the Drawings
Fig. 1 is a perspective view showing the **trans** **tracheal** **catheter** of this invention mounted through the skin and into the trachea of a patient and showing the **oxygen** supply connecting **tube** secured to the patient's wearing apparel between the connection to the **trans** **tracheal** **catheter** and the connector to a supply of **oxygen** ;
Fig. 2 is a diagrammatical illustration of the infiltration of a local anesthetic into the...needle is removed;

Fig* 5 is a diagrammatical illustration of the in sertion of the **stent** over the guide wire after removal of the dilator;
Fig. 6 is a diagrammatical illustration of the in sertion of a temporary **transtracheal catheter** after removal of the **stent** .;
Fig. 7 is a diagrammatical illustration of the in sertion of the final **catheter** ,, after removal of the temporary **catheter** ;
Fig. 8 is a diagrammatic view of the trachea with a flush-mounted prior art **catheter** showing the orienta tion of the **catheter** and the f low of **oxygen** to the patient from the **catheter** ;
Fig. 9 is a diagrammatic view of the trachea,, similar to Fig. 8, but showing the thorough.mixing of **oxygen**0 and air by means of the **catheter** of this invention;
Fig. 10 is a side elevation of guide wire which forms a...

...which
forms a part of the first kit of this invention, for use in the **method** of **implanting** the **transtracheal catheter** of this invention;
Fig. 12 is an end view of the distal end of the dilator of Fig. 11;
Fig. 13 is a side elevation of a **stent** which forms a part of the first kit of this invention;
Fig. 14 is a...

...a second kit of this invention;
Fig. 15 is a side elevation of a temporary **catheter** which forms a part of the second kit of this invention;
Fig. 16 is a side elevation of a removable, final **catheter** which forms a part of the third kit of this invention;
Fig. 17 is an...

...section, taken
along line 19-19 of Fig. 16 showing an attachment means for the **transtracheal catheter** .

Fig. 20 is a graph comparing **oxygen therapy** by an analysis of blood **oxygen** during exercise of the **catheter** of the present invention compared to other **therapies** .

Fig* 21 is another embodiment of a reinforced **catheter** useful in the practice of the present invention.

Figo 22 is a partial sectioned view...

...Invention
As best seen in Fig. 1, a patient P has been fitted with a **transtracheal catheter** C. The **catheter** includes a flexible reinforced **tube** 10 having a plural ity of openings -12 at the distal end thereof. These openings have a 'specific orientati7on to facilitate the mixing of the **oxygen** with the air being breathed by the patient, as more fully explained hereinafter. The distal...

...a tract in the
trachea 14, is positioned above the carina 15 to supply
the **oxygen** equally to the right and left bronchus 16
and 17. The **catheter** is **inserted** into the cervical
trachea, in a manner more fully described hereinafter.

After **insertion** , attachment means 18." is used to secure
the **catheter** C to the patient I s: neck by means of a
chain 20 extending around the patient's neck.

The proximate end of **catheter** C extends away from
the patient's body and has a connector 24 attached to
tube 10 through which **oxygen** is supplied to the patient.

Preferably, **tube** 10 is reinforced, and most preferably,
is reinforced by a coil **inserted** snuggly internally
into the lumen. As is readily apparent, the extension
provided, makes it possible...

...to see
connector 24 over his chin so as to connect and discon
nect the **oxygen** supply **tube** and to even remove the
catheter , as an outpatient, at home, for cleaning and
then replace it and reconnect the **oxygen** supply. The
source of **oxygen** can be from any source of **oxygen** such
as pressurized **oxygen** tanks, liquid **oxygen** reservoirs
or **oxygen** concentrators.. with some minor variation in
the prescribed flow rates.

As shown in Fig. 1, an intermediate reinforced
tube 26 is provided which is connected between connector
24 through clip 30 which is shown...

...30 can be attached directly to
the patient's wearing apparel instead of using a
supplemental belt. The connector 34 is then connected
to **tube** 36 to **oxygen** supply 38. The purpose of this
structure is to assure that as the patient moves...

...p4tient will not move to the limit,of the tubing
and place a stress on **catheter** C which could pull the
catheter out of the trachea and perhaps cause injury or
discomfort to the patient, With the intermediate
tubing arrangement as shown, any tension would be
placed on **tube** 36 and not on **tube** 26. In addition, the
connector 24 is designed to disengage this also when
subjected to a 1 to 3 pound pull.

The **catheter system** of the present invention
includes two **catheters** . The first is referred to
herein as a temporary **catheter** which is used for a
limited period of time while the tract or fistula
formed through the trachea heals. The second **catheter**
is referred to as the final **catheter** which is capable
of being used by the patienz on a long-term basis but...

...by the patient, at home, for cleaning on
a periodic basis. The differences in these **catheters**
will be more fully explained hereinafter, Both cathe
ters are made of the same material differences, have the same dimensions.

In this regard,
for an adult patient, the **catheter** will have a length of approximately 20 cm and be made preferably of polyurethane, or...

...80 and about 90, The attachment
means 18" is located near the midpoint of the **tube** after placement and is approximately 9 cm from connector 24 on the proximate end of the **tube** and approximately 11 cm from the distal end of the **tube** when in place in the trachea, For an adult, the preferred diameter is an 8 French **catheter** . In some instances, it is contem plated that the inside diameter might be as small...

...Of course, the length would be correspondingly shorter to prevent the problems previously discussed.

The **method** of **inserting** **transtracheal** **catheter** C is best illustrated in Figs. 2 Conveniently, the **method** can be carried out by using apparatus contained in three kits. The first kit contains a hypodermic needle, a guide' wire, a dilator and a **stent** . The second kit contains the temporary **catheter** and a cleaning rod. A final **catheter** and a cleaning rod are contained in the third kit, In Fig. 2, a local...

...of
the needlef the possibility of hemorrhaging is greatly reduced even though the tissue being **penetrated** is vascular. A 32 cm straight guide wire 42 is passed through the 18 gauge...

...the
trachea as seen in Fig, 3, The bevel on the needle and angle of **insertion** are exploited to direct the guide wire downwardly into the trachea. Conveniently, indicia, such as...

...designed not to scratch or
otherwise injure the mucosa or trachea when the wire is **inserted** . This atraumatic end is preferably about ...cm from the atrai;matic end to
help the physician determine the proper depth of **insertion** .

Next, preferably a 10 French by 15 cm long Teflon dilator D, found in the...

...small tract or fistula
created by the hypodermic needle 40 is generally enlarged by the **insertion** of the taper of distal end 45 of the dilator into the tract, As the dilator is **inserted** safely by the physician to the mark 48, previously described, see Fig. 11f the tract...

...minute to
accomplish sufficient stretching of the tissue.

Next the dilator is removed and the **stent** S I the final element of the fist kit, is passed over the guide

wire...

...through the tract into the tracheal as best seen in Fig. 5. The structure of stent St with attached flange 18 is Illustrated in Figs. 13.

The flange 18 serves to stabilize the **stent** by sutures placed through its eyelets and adapts to Luer taper connectors for instillation of lidocaine to suppress coughing. The **stent** has a body 51 which is made of sufficiently rigid material to hold the tract which has been formed in the trachea open. This **stent** body 51 has, preferably, a 9 French diameter and is preferably about 11 cm long...

...distal tapered end 52 to the proximal end 50. The tapered end 52 facili tates **insertion** of **stent** S through the tract in the trachea, A passageway 53 extends through the **stent** and is maintained open to allow air to pass out of the patient and prevent...

...the skin to minimize the danger of the patient experiencing subcu taneous emphysema, during the **process** , After typically one week, or longer if indicated, **stent** S is removed by the physician and a temporary **catheter** T is **inserted** , as shown in Fig. 6. The structure of this **catheter** is best seen by reference to Fig, 16, The temporary **catheter** is longer than the **stent** , being about 20 cm in length. In fact, the length of the distal end 54 temporary **catheter** T which rests inside the trachea is approximately 11 cm long, which is the same length as the distal end of the **stent** . The temporary **catheter** has a connector 56 at the proximate end 58 thereof for attachment to an **oxygen** supply. The extra length of tubing provided by proximate end 58 makes it possible ...the patient to see connector 56 so that he can easily connect or disconnect the **oxygen** supply and can clean the **catheter** , as described below.

This **catheter** also has a longitudinal passageway 60 extending its entire length and is provided with reinforcing...

...within the tubular material that forms proximate end 58 and distal end 54 of temporary **catheter** To The purpose of this armoring is to reduce the possibility of the **catheter** collapsing, or kinking from any manipulation done by the patient to thereby help assure a constant supply of **oxygen** to the patient by keeping a constant cross-sectional area in the **catheter** lumen. This is important since this device will be used by an outpatient who will...

...shown in Figs. 21 and 22 illustrate another structure for reinforcing predetermined portions of the **catheter** against kinking or collapsing during use. The flange 98 (which is shaped and structured as...

...reinforcing means 91 (shown in phantom in Rig. 22), which snuggly surroundsothe outside of the **tube** 95, to provide kink and collapse resistance to the **tube** 95during use,

Referring again to Fig. 21, the preferred extent of placement of the external reinforcing means 91 to provide the desired reinforcement for the **catheter tube** 95, is shown. It is contemplated that up to about three inches of coil reinforcement...

...portion 54 has a taper 62 which is longer on the posterior side to facilitate **insertion** and also to deflect the **oxygen** introduced through the **catheter** away from the mucosa at the back of the trachea and to direct the **oxygen** downwardly and slightly forwardly. After proper positioning the temporary **catheter** T is connected to a source of **oxygen** , The **oxygen** flow is then adjusted to achieve a blood **oxygen** saturation of at least 90% by ear oximetry or arterial blood gas analysis.

Since **oxygen** is now being supplied to the patient throug temporary **catheter** T, it is necessary to keep passageway or lumen 60 open. This is accomplished by...

...the shaft 64. Shaft 64 is slightly longer than the total length of the temporary **catheter** To To clean out the **catheter** , the **oxygen** is discon nected and the shaft 64 of cleaning rod R is a **inserted** through ...After cleaning, the cleaning rod R is removed and the connector 56 is reconnected to **oxygen** supply.

The temporary **catheter** with flange 181 and rein forced as described, is preferably kept in place for six...

...trachea can heal completely. After complete healing has occurred, the physician removes the tempo rary **catheter** T and provides the patient with a final ca-theter C which is **inserted** and positioned as shown in Fig, 7* This **catheter** is similar to the temporary **catheter** T with certain differences, as enumerated below.

The structure of the final **transtracheal catheter** C, which is a part of the third kit, is shown in Figs.

16-19, The **catheter tube** 10 is also reinforced, preferably by means such as a coil spring 72 which is...

...this armoring is also intended to reduce the possibility of collapse or kinking of the **trans tracheal catheter** which could restrict the **oxygen** supply to the patient, Conveniently, coil spring 72 extends a sufficient distance along the length of **tube** 10 to provide the described features with f lange or fastening means 18" located at...

...an aperture
74 (Fig* 19) for receiving a chain 20,, or other holding means. The **catheter tube** 10 is provided with a longi tudinal passageway or lumen 76 and the distal end has a taper 78 with a longer posterior side for directing the **oxygen** away from the mucosa of the trachea. A plurality of openings 12 are spaced about the anterior side of the **catheter** through an arc of approximately 120' and are all positioned on the portion of the...

...within 60' to
either side of a midline 80 on the anterior side of the **tube** 10, as shown in Fig, 18*
The distinct advantage of this arrangement will be apparent from a viewing of Figs, 8 and 9. In Fig. 8, a prior art **catheter** K is shown having a tubular body member 82 with a flat distal end 84 and no openings in the sidewall. As can be seen, most of the **oxygen** is directed straight downwardly in a stream into the right main stream bronchus 16 since...shown
by arrows 86, will be less likely to effectively mix with the stream of **oxygen** from the distal end 84 of **catheter** K as shown by arrows 88.
on the other hand, in applicant's preferred embodiment, shown in Fig. 9, **oxygen** is discharged from **catheter** C through the beveled or tapered distal end 78 and openings 12 so as to...

...the patient's
natural breathing, as indicated by arrows 92. This will occur because @he **oxygen** is issued in multi directional streams so that a substantial equal amount of **oxygen** enriched air passes essentially uniformly into both the right bronchus 16 and the left bronchus 17 and minimizes the drying effect of **oxygen** on the mucous membranes.

Another important distinction between the prior art **catheter** K and **catheter** C is that the connector of **catheter** K is flush against the trachea whereas the proximate end or extension 68 of **catheter** C extends outwardly for about 9 cm, This makes **catheter** C suitable for outpatient use., whereas **catheter** -K is not.

With extension 68, the patient can see connector 24 over his chin so that he can connect and disconnect the **oxygen** supply ea'sily and can periodically remove the **catheter** for cleaning.

oxygen is delivered at very low pressures, such as below 2 psi and at low f low rates, which are usually 50% or less than that which is required with a **cannula** .

Of course, the **catheter** is only for use by a spontane ously breathing outpatient. Individuals who require more than 3 liters per minute by **transtracheal** catheter either at rest or during exercise can receive up to 6 8 1/min. with the **catheter** of the present inventions.

it can be seen from this chart that with the same flow

rates in liters per minute for the 16 gauge **catheter** and the **catheter** of the present invention, blood oxygenation is improved for the described device. The nasal **cannulae** is clearly not as effective as the **transtracheal catheters** of the present invention even if operated at higher flow rates. Thus, a substantial savings can be obtained from reduced **oxygen** use while providing active patients with better blood gas values during the **therapy** . Used on a long-term basis, this difference in efficiency should produce even more advantages...

...of useful life.

From the foregoing, the advantages of this invention are readily apparent. A **transtracheal catheter** has been provided which is safe and comfortable for a spontaneously breathing patient and can be installed in a doctor's office on an outpatient basis without requiring hospitalization. A **method** of installation is provided whereby the **transtracheal catheter** may be **inserted** under a local anesthetic,, with the patient remaining ambulatory. Because of its small size, **insertion** can be accomplished with no risk of severing a.-Li artery. The **transtracheal catheter** iso armored so that the possibility of kinking and crushing' is min imized to assure a continuous supply of **oxygen** to the patient, Furthermore, i@ is convenient for the device to be removed by the patient for cleaning and reinsertion. Disconnection and reconnection of the **oxygen** supply is facilitated by the extension of the external end, The constant flow of low pressure **oxygen** into the collapsed airways of emphysema patients helps hold the bronchial **tubes** open to improve the function of the lungs and reduce the work of breathing.

The above-described **method** is accomplished by the use of devices which are provided in a first, second and...

...which
is passed over the guide wire and used to enlarge the tract; and a **stent** to replace the dilator. A second kit is provided which includes a temporary **catheter** which replaces the **stent** and remains in place for a period of several weeks while healing of the tract is completed; a cleaning rod f or cleaning the temporary **catheter** ; the third kit includes a removable,, f inal **catheter** which replaces the temporary **catheter** af ter the healing is complete and a cleaning rod.
An important feature of this **method** is that it allows a small **catheter** to be **inserted** by using an even smaller needle to f o--@ a tract which is subsequently dilated. The prior art , on the other hand, requires either a large needle for a smaller **catheter** or a large tract for a large tracheotomy **tube** to resuscitate a non-breathing patient. I
The f irst kit is an **Insertion** Tray that provides all the supplies less sterile gloves and facial tissue necessary to create a tract for the **transtracheal**

catheters of the present invention. The paper drape around the tray may be opened to serve as a Mayo stand cover. The **Insertion** Tray has two tiers . The upper preparatory Tier should be used clean and provides the supplies for punc@ure site selection; local anesthesia and skin preparation. The Lower and second **Procedure** Tier should be used sterile and provides the supplies to create a **catheter** tract and stabilize the stenting device.

The upper tier will preferably contain a surgical marking...11cm; 10 French x 15 cm tissue dilator marked at 8cm; Lubafax packet; 9 French **stent** ; Disposable needle holder; Disposable scissor; 3-0 Nylon suture on FS-1 needle; and a H bandage.

The **Insertion** Tray therefore provides all the supplies less sterile gloves and facial tissue necessary to create a tract for the' **transtracheal catheters** .

Most of the items included in the tray are commercially available and are gathered in an orderly sequence for the convenience of the physician.

MANUFACTURERS OF **IN**SERTION TRAY COMPONENTS
Surgical Marking Pen Devon Industries
Chatsworth, CA 91311
Stainless Steel bead chain McMaster...

...constructed as de
scribed, with biocompatible materials where necessary,
For example, the temporary and permanent **catheters** are
3 5 preferably const-ructed as described from medical grade polyurethane which is coated...
...which are exposed to tracheal secretions.

The polymer provides a lubricious surface for ease of **insertion** and removal. The polymer, also minimizes adherence of mucous to the **catheter** ,
The bevel of the tip of temporary and permanent **catheters** , and the side ports of the permanent **catheter** direct **oxygen** away from the tracheal mucosa toward the center of the air column in the trachea...taper connector is a feature which will
rdsult in a safety dis@onnect rather than **catheter** dislodgement in the event of an excessive pull on the proximal end of the **Oxygen Hose** ,
The Cleaning Rod is designed to remove debris as it is passed through the lumen of either the temporary or permanent **catheter** , The length is preferably 5mm longer than the **catheter** ., and over- **insertion** or loss down the **catheter** is prevented by the 2cm handle which is at a 90' angle and the small cap at the end of the handle.

Both, the temporary and permanent **catheters** of the present invention are most preferably 8 French rein forced **tubes** made of medical grade clear polyurethane with nylon coil spring reinforcement and approximately 20cm (7...

...means or security flange is most
preferably made of Kraton or polyethylene, and is
clear.

Procedure

Candidates for this **procedure** should demonstrate a need for chronic **oxygen therapy** by having arterial blood gases analysis of PaO 2 of less than-55 Torr and a SaO2 analysis of less than 90% on room air during appropriate medical **therapy** . The use of **transtracheal oxygen** of f ers the patient greater mobility,, improved cosmesis, and avoidance of nasal irritation by **cannulae** . Patients who are inadequately oxygenated with nasal **cannulae** or 16 gauge **transtracheal catheters** may benef it from better oxygenation with the **catheter** of the present invention, The recommended pre- **puncture** evaluations should identify individuals for whom **transtracheal oxygen therapy** is contraindicated and others who require special considerations in the course of treatment.

The **Puncture** Tedhnique uses an 18 gauge needle wire guide and dilator to stretch an opening into the trachea with minimal discomfort. About one hour before the **puncture** , the patient is given is given oral prophylactic antibiotic with a sip of water. If...

...patient
removes his top and puts on a hospital gown. He is seated in a **p**rocedure chair with a head restt and the head is elevated slightly to reproduce the position of the neck. while looking in a mirror during **catheter** changes. **oxygen** is continued throughout the **procedure** , but **cannulae** are repositioned so that they arrive from behind the head and do not interfere with the anterior neck. The **Insertion** Tray is removed from its plastic bag and placed on a Mayo stand at **chest** level in front of the patient. The paper wrapping is opened fully to act as...trapezius muscles, and
the intersection of the cervical trachea and necklace is marked for subsequent **puncture** . The highest acceptable **puncture** should be the tracheal interspace immedi
ately below the cricoid cartilage (cricotracheal ligament),, and the...

...the
manubrium. occasionally a less snug necklace will be required to reach a low cricotracheal **puncture** site, A second length of bead chain is included for occasions when the first is...

...is removed and placed in a labeled envelope for later use, The skin over the **punctur4** ` site is prepared T@dth an alcohol swab without removing the orientation marks.

The prefilled...

...cough, bad taste and globus sensation
caused by the local anesthetic. The needle is passed

transtracheally at the **puncture** site, and the remainder of local anesthetic q@.ickly deposited onto the tracheal mucosao A...

...is preferred to various iodophors because it is nonstaining and better suited for this outpatient **procedure** , The skin is then blotted dry with gauze so that the **procedure** drape will stick to the skin. The upper Preparatory Tier is then removed f rom...

...sterile. Surgical gloves are put on, and the Steri-Drape is applied to the upper **chest** at the level of the clavicles.

A 1 cm vertical incision centered at the **puncture** site is made with a #15 scalpel. Gauze sponge is held in the palm of...After one minute of stretching, the dilator is removed and exchanged for the 9 French **stent** , **Insertion** of the **stent** is facilitated by a small amount of water soluble Jelly on its tip and J...

...guide is then removed. The disposable needle holder and scissor are used to suture the **stent** to the skin with 3-0 nylon suture.

Sutures can be placed through each of 2 eyelets on a flange of the **stent** taking care not to close the midline incision. - The skin and lumen of the **stent** should remain open to minimize the risk of **subcutaneous** emphysema. The H-bandage is then applied taking similar care not to create an occlusive dressing* The patient is sent to the radiology department for posteroanterior and lateral **chest** xrays to document **catheter** position and absence of pneumothorax and **subcutaneous** emphysema. Nasal **cannulae** **oxygen** is continued during the **stent** week, and **oxygen** should not be administered through the **stent** , Significant bleeding has not been observed because the **method** is relatively atraumatic, Because the **stent** functions as a drain, bacterial infection of the tract has not been observed.

After one week of stenting, the temporary **trans** **tracheal** **catheter** is **inserted** by the physician over a wire guide, and **transtracheal** **oxygen** **therapy** is begun.

The temporary **catheter** is designed to remain in place during the early weeks of **transtracheal** **oxygen** **therapy** when the tract is maturing. The **catheter** is cleaned in place using the Cleaning Rod and steril4 saline.' The kink and crush resistant **Oxygen** **Hose** adapts standard **oxygen** sources to the **catheter** , Inadvertent decannu lation is protected against by the suspender-type security clip which attaches to...

...or dress and the 2 pound safety release of the Luer taper connector between the **hose** and the **catheter** , In summary, the durometer values, i.e. about

80-90,, selected for the final configurations of the temporary and permanent **catheters** of the present invention are desirable and indeed necessary for proper **insertion** and long-term patient comfort. In this regard, the spacing for the location of the holes of the distal end of the permanent **catheter** are preselected, within the range of orientation described, to retain a sufficient flexibility and stiffness to facilitate proper **insertion** , removal and cleaning! as well as enabling proper orientation, when in place, in order to achieve the benefits described herein. The 8 French size of the temporary and permanent **catheters** is the most preferred size since tests have shown that it is the smallest diameter compatible with back pressure limits, for a preselected range of **oxygen** flow rates.

Claim
le An apparatus for supplying **supplemental** **oxygen** to a patient f rom a portable supply of **oxygen** which is capable of being carried by such patient, and which **oxygen** is capable of being introduced uniformly into both of the lungs of such atient on a continuous p
long term daily basis by conduction of **supplemental** **oxygen** into the cervical trachea through a **catheter** .disposed in the trachea in a downwardly extending position in the trachea with a distal end portion of such **catheter** - located in the trachea immediately above the carina and configured to promote adequate mixing of the **oxygen** introduced with the air from a normally breathing patient, the **catheter** apparatus comprising: elongated flexible **tube** means having a durometer of from about 80 to about 90 and a length sufficient...

...end portion
outwardly of the neck for attachment of the proximate end portion to a **tube** connected to a portable supply of **oxygen** carried by the person; the **tube** means of said **catheter** having a continuous smooth cylindrical outer peripheral surface and a lumen having a continuous smooth...

...3 * 0 millimeters and an
inside diameter of between 1,7 and 2,5 millimeters;
oxygen outlet opening, means at the distal end portion of the tubular means including a downwardly and generally anteriorly facing end opening of the same diameter as said continuous **oxygen** passage means when said **tube** means is in place in the trachea, and said distal end portion of said **tube** means additionally containing a plurality of openings located in predetermined spaced relationship above said end...

...said sidewall and facing
generally forwardly toward the anterior portion of

the trachea for supplying **oxygen** only in a f orwardly f acing direction whereby rearward f low of **oxygen** %toward the posterior portion 6f the trachea is limited to prevent mucosal damage; said **tube** means additionally containing reinforcement means for maintaining a constant lumen cross-section in at least a portion of said **tube** means by resisting restriction of said central passage means in order to maintain said continuous constant diameter of said central passage means during **oxygen** **therapy** use; and said **tube** means also preferably being provided with hydrophilic coating means on at least the distal end...

...of mucous-type materials present in the trachea which would otherwise restrict the flow of **oxygen** through said **tube** means.

, The invention as defined in claim 1 and further comprising:

inclined end surf ace...and said elliptical end opening facing forwardly toward the front of the trachea for directing **oxygen** toward the front of the trachea while restricting **oxygen** flow 'toward the back of the trachea.

3e The invention as defined in claim 2...

...substantially midway between the opposite side surface portions of said tubular means; and

said intermediate **oxygen** openings being located at approximately between 301 to 60' on either side of said end opening whereby **oxygen** is delivered along a forwardly facing arcuate supply zone having an included angle of between...

...means extending around the neck of the person for holding said tubular means;

a first **tube** locating and connection means on said attachment means and a second **tube** location and connection means on the proximate end portion of said **tube** means for supportively connecting said **tube** means to said strap means and for locating said end port and said side ports in said **oxygen** supply position. 5* A **system** for providing a continuous supple mental supply of low pressure **oxygen** at a relatively low flow rate to a person having chronic **hypoxemia** from a portable low pressure **oxygen** container carried on the body of the person which comprises:

an elongated **transtracheal** **tube** means having an elongated continuous constant diameter central passage means extending between an **oxygen** inlet opening means at a proximate end portion of said **transtracheal** **tube** means and an **oxygen** outlet opening means at a distal end portion of. said **transtracheal** **tube** means, for mounting on and into the body of a person by **insertion** of said distal end pQrti6n into the trachea of the person through an **insertion** opening #in the skin of the person located in the cervical trachea of the person for supplying **oxygen** to the person;

a locating attachment means f ixedly mounted
on an intermediate portion of said **transtracheal**
tube means for locating said **transtracheal** **tube**
means relative to the **insertion** opening in the
skin by abutting engagement with the skin circum
jacent the **insertion** opening in the skin and for
separating said **trans**tracheal tube means into an
elongated **subcutaneous** tubular means portion,
including said distal end portion located on one
side of said locating/abutment means for mounting
in the trachea and for further separating said
tracheal **tube** means into an external tubular means
portion, including said proximate end portion, for
connection to the **oxygen** supply;
said **subcutaneous** tubular means 'portion
having a length between said locating/abutment
means and said distal end portion such as to
locate said **oxygen** discharge opening means in the
trachea below the cricoid cartilage in upwardly
spaced relationship to...length between said attachment means and said
proximate end portion such as to space said **oxygen**
inlet means a sufficient distance away from the
tract in the skin to enable flexible displacement
of said external means relative to said attachment
means without causing displacement of said
subcutaneous tubular means portion;
said attachment means including neck support
means for mounting around the neck...

...for connection to said attachment means
and for holding said attachment means proximate to
the **insertion** openi4g in the skin;
a coupling means on said proximate end
portion of said **oxygen** supply **transtracheal** **tube**
means for releasable connection to said **oxygen**
supply means; and
an external **oxygen** supply **tube** means for
mounting on the body of the person and having
disconnectible coupling means for coupling said
external **oxygen** supply **tube** means to said **trans**
tracheal **oxygen** supply **tube** means whereby **oxygen**
can be supplied to said **transtracheal** **oxygen**
supply **tube** means.

6 A first kit for use in the placement of a
percutaneous small bore, **transtracheal** **catheter** for
transtracheal , low flow, low pressure **oxygen** delivery
to a spontaneous breathing patient with chronic
hypoxemia , said first kit comprising:
a hypodermic needle having a diameter'smaller
than that of the **catheter** to be **ins**erted for
forming
an initial tract through the trachea of
the patient and injecting an anesthetic...

...portion with a
proximate end, said guide wire being sized to be
capable of being **inserted** through said needle to
maintain the tract after said needle is withdrawn
over said proximate...

...distal end than its
proximate end, and having a diameter that is
larger than the **catheter** to be **inserted** , and has a
central passageway for reception of said dilator
over said guide wire so...

...into
the tract to enlarge or dilate the opening by
stretching the tissue; and
a **stent** . having a tubular body tnade of semi
rigid material with an outside diameter slightly
less than the diameter of said the dilator but
larger than the diameter of the **catheter** to be
inserted , so that it can be **inserted** through the
enlarged tract into the trachea the length of said
stent being such that the distal end thereof is
positioned in the trachea just above the carina.

7 A second kit comprising:
a temporary **catheter** made of a flexible
material having a predetermined flexibility and
having a tubular body with...

...as said distal end
portion, a first end connection for attachment to
a supply of **oxygen** , said proximate end portion
being of sufficient length that said end
connection can be seen by the patient for
connecting and disconnecting the **oxygen** supply
when said temporary **catheter** is in place, and an
attaching means connected to said temporary
catheter at the juncture of said proximate and
distal end portions for connection to said
fastening means to hold said temporary **catheter** in
place;
a cleaning rod having a body member having a
preselected length compared to said temporary
catheter and having an outside diameter slightly
less than the inside diameter of said temporary
catheter which is capable of expelling mucosa
build-up in the lumen of said temporary **catheter**
for periodic cleaning of said temporary **catheter**
by disconnecting the **oxygen** supply and **inserting**
said cleaning rod through said end connection.

8 'A third kit comprising:
a removable,'final **catheter** of identical size
as said temporary **catheter** andifurther including a
plurality of spaced openings in said lower body
adjacent the distal end...

...thereof to prevent leakage at the surface of
the neck and to promote mixing of **oxygen**
discharged through said openings with air inhaled
by the patient during regular breathing, while
maintaining...

...end to
indicate to the physician the proper depth to

which the dilator should be inserted in the opening in the trachea; and
said dilator has an outside diameter of 10...

...A first kit, as claimed in claim 1, wherein the attaching means connected to said **stent** includes:
a flange surrounding said tubular body adjacent said proximate end; and
J
a pair of spaced apertures f or relceiving said fastening means to secure said **stent** in position.

12 A second kit, as claimed in claim -2 , wherein said temporary **catheter** includes:
a tapered distal end which is longer on the posterior side for directing a stream of **oxygen** introduced through said temporary **catheter** away from the mucosa on the posterior side of the trachea; and
a cleaning rod.

13 A third kit, as claimed in claim 2, wherein said final **catheter** includes:
a tapered distal end which is longer on the posterior side for directing a stream of **oxygen** introduced through said final **catheter** away from the mucosa on the posterior side of the trachea.
, A third kit, as...about the midline of the anterior side of said distal end.
17 A large bore **transtracheal catheter** for providing low flow, low pressure **oxygen** deLivery to a spontaneously breathing patients requiring **supplemental oxygen therapy** , said **catheter** comprising:
an elongated tubular body made of a medical grade flexible material having:
a proximate...

...on the proximate end of said proximate end of said proximate portion for connecting said **catheter** to a low flow, low pressure source of **oxygen** , said proximate portion being of sufficient length that said connector can be seen by the patient for connecting and disconnecting the **oxygen** supply when said **catheter** is in place;
a distal portion formed integrally with and of a preselected length for...

...just above the carina with a longer portion thereof on the posterior side for directing **oxygen** away from the mucosa and substantially uniformly into the bronchi;
attaching means at the juncture of said proximate portion and said distal portion for holding said **catheter** in place; and
said attaching means including fastening means extendible around the patient's neck to secure the **catheter** in place.

18 A **catheter** , as claimed in claim 12, further including:
a thin wall of flexible plastic material;
reinforcing...

...protect against collapsing and
kinking of the central lumen of said tubular body.
19e A **catheter** , as claimed in claim 18, further including:
a plurality of openings in said wall between...

...about said
periphery of said distal end only on the anterior side thereof.
20 A **catheter** , as claimed in claim 19, wherein:
said plurality of openings are spaced both longitudinally and peripherally.
21a A **catheter** , as claimed in claim 19, wherein:
said plurality of openings are spaced periph erally through...

...in either
direction about the midline of the anterior side of said distal end.
* A **method** of **inserting** a **transtracheal** **catheter** into the trachea of a spontaneously breathing patient with chronic **hypox**emia , said **method** comprising the steps of:
infiltrating the soft tissue overlying the cervical trachea;
advancing a hypodermic...

...the trachea to form a
tract;
injecting local anesthesia into the trachea through the needle;
inserting a guide wire through the needle;
removing the needle over the guide wire;
inserting a tissue dilator over the guide wire and through the tract ...for a sufficient period of time to enlarge the tract by stretching the surrounding tissue;
inserting a **stent** over the guide wire through* the tract to maintain the tract during healling;
and
removal of guide wire; and
securing the **stent** in place in the tract.

23 A **method** , as claimed in claim 22, including the further steps of:
removing the **stent** from the tract after initial healing has occurred;
inserting a **transtracheal** **catheter** through the enlarged tract; and
connecting a supply of low pressure, low flow **oxygen** to the **transtracheal** **catheter** .

24 A **method** , as claimed in claim 22, including the further steps of:
attaching a syringe, which contains the local

anesthetic! to the needle prior to **insertion** ; and
removing the syringe from the needle after
injection of the anesthetic into the trachea.

25 A **method** , as claimed in claim 23, including
the further steps of:
securing the **catheter** around the patient's
neck after **insertion** against movement.

26 A **method** ,, as claimed in claim 23, wherein
said **transtracheal** **catheter** is a temporary **catheter** ,,
including the further steps of:
disconnecting the supply of **oxygen** from the
temporary **catheter** ;
removing the temporary **catheter** after the
tract in the trachea has healed;
inserting a final **catheter** through the tract
and into the trachea, which final **catheter** can be
removed by the patient for short periods of time
for cleaning; and
reconnecting the supply of **oxygen** to the
permanent **catheter** .

27 A **method** , as claimed in claim 2.3, wherein:
the needle is an 18 gauge thin wall...

...of the dilator is approximately 10
French by 15 cm long;
the size of the **stent** is approximately 9
French by 11 cm long; and
the size of both the temporary **catheter** and
the final **catheter** is approximately 8 French
having a total length of about 20 cm, with a lower
distal end which is about 11 cm long for **insertion**
through the tract and into the trachea 'and an
upper proximate end which is 9 cm long to
facilitate connection and disconnection of **oxygen**
by the patient.
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26/3,K/31 (Item 31 from file: 349)
DIALOG(R)File 349:PCT FULLTEXT

00780804 **Image available**
AGENTS FOR THE ENHANCED OXYGEN **DELIVERY IN MAMMALS**
RENFORCEMENT DE L'APPORT EN OXYGENE CHEZ DES MAMMIFERES, PROCEDES ET REACTIFS CORRESPONDANTS

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AGENTS FOR THE ENHANCED OXYGEN **DELIVERY IN MAMMALS**
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Detailed Description
Claims

English Abstract
The present invention comprises compounds, compositions thereof, and **methods** capable of delivering a broad range of anionic molecules to the cytoplasm of mammalian cells. In certain embodiments, the present invention relates to compounds, compositions thereof, and **methods** that enhance the ability of mammalian red blood cells to deliver **oxygen** , by delivering a ligand for the allosteric site of hemoglobin to the cytoplasm of the...

Detailed Description
... beginupon receipt of that report. ning of each regular issue of the PCT Gazette.

Enhanced **Oxygen** Delivery in Mammals, **Methods** and Reagents Related Thereto
Related Applications
This application claims the benefit of priority to United...

...25, 1999.

Background of the Invention

1schemia

Ischemic insult, i.e., the localized deficiency of **oxygen** to an organ or skeletal tissue, is a common and important problem in many clinical...

...organ is removed from a body, isolated from a blood source, and thereby deprived of **oxygen** and nutrients for an extended period of time.

Ischemic insult also occurs in certain clinical...

...response to infection (tachycardia, tachypnea alterations in temperature and leukocytosis) and those related to organ- **system** dysfunction (cardiovascular, respiratory, renal, hepatic and hematologic abnormalities). Furthermore, the lipopolysaccharide (LPS) of gram-negative...

...hemoglobinopathy with hemoglobin S instead of normal hemoglobin A. Sickle cell anemia is associated with **hypoxia** because of decreased **oxygen** tension with hemoglobin S. This condition leads to a systemic hypoxic condition. The viscosity of...

...blood supply to the myocardium (the muscles of the heart) to meet its demand for **oxygen** . The ultimate result of persistent myocardial ischernia is necrosis or death of a portion of...

...blockage or rupture, part of the brain fails to get the supply of blood and **oxygen** that it requires. Brain tissue that receives an inadequate supply of blood is said to be ischemic. Deprived of **oxygen** and nutrients, nerve cells and other cell types within the brain begin to fail, creating...

...a catastrophic stroke or heart attack results.

Hemozlobin

Hemoglobin is a tetrameric protein which delivers **oxygen** via an allosteric mechanism.

Oxygen binds to the four hemes of the hemoglobin molecule. Each heme contains porphyrin and iron in the ferrous state. The ferrous iron-**oxygen** bond is readily reversible. Binding of the first **oxygen** to a heme releases much greater energy than binding of the second **oxygen** molecule, io binding of the third **oxygen** releases even less energy, and binding of the fourth **oxygen** releases the least energy.

In blood, hemoglobin ...tense) state, hemoglobin is deoxygenated. In the "R" (for relaxed) state, hemoglobin is oxygenated. An **oxygen** equilibrium curve can be scanned to observe the affinity and degree of cooperativity (allosteric action...

...plots the percent of hemoglobin oxygenation and the X-axis plots the partial pressure of **oxygen** in millimeters of mercury (mm Hg). If a horizontal line is drawn from the 50% **oxygen** saturation point to the scanned curve and a vertical line is drawn from the intersection...

...is the pressure in mm Hg when the scanned hemoglobin sample is 50% saturated with **oxygen**). Under physiological conditions (i.e., 37 C, pH = 7.4, and partial carbon dioxide pressure...

...tested, the scanned curve is considered to be "left-shifted" and the presence of high **oxygen** -affinity hemoglobin is indicated. Conversely, if a higher than normal P50 value is obtained for...

...tested, the scanned curve is considered to be "right-shifted", indicating the presence of low **oxygen** -affinity hemoglobin.

It has been proposed that influencing the allostenic equilibrium of hemoglobin is a...

...to have general utility in a variety of disease states where tissues suffer from low **oxygen** tension, such as ischemia and radio sensitization of tumors. Several synthetic compounds have been identified ...

...the allosteric regulation of hemoglobin and other proteins. For example, 3 several new compounds and **methods** for treating sickle cell anemia which involve the allosteric regulation of hemoglobin are reported in...
...pp. 163-164, and Lalezari et al., "LRI6, a compound with potent effects on the **oxygen** affinity of hemoglobin, on blood cholesterol, and on low density lipoprotein", Proc. Natl. Acad. Sci...

...known I 0 antihyperlipoproteinemia drug, bezafibrate, is capable of lowering the affinity of hemoglobin for **oxygen** (See "Bezafibrate lowers **oxygen** affinity of hemoglobin", Lancet 1983, 88 1).

Human normal adult hemoglobin ("I-IbA") is a...

...iron atom is susceptible to oxidation, but may be reduced again by one of two **systems** within the erythrocyte, the cytochrome b5, and glutathione reduction **systems** .

Hemoglobin is able to alter its **oxygen** affinity, thereby increasing the efficiency of **oxygen** transport in the body due to its dependence on 2,3-DPG, an allosteric regulator...

...3-DPG is present within erythrocytes at a concentration that facilitates hemoglobin to release bound **oxygen** to tissues. Naturally-occurring hemoglobin includes any hemoglobin identical to hemoglobin naturally existing within a...
...by humans. The naturally-occurring hemoglobin of the present invention is not limited by the **methods** by which it is produced. Such **methods** typically include, for example, erythrocytolysis and purification, recombinant production, and protein synthesis.

It is known...

...237, p. 146, 1972).

The binding of these polyanionic molecules is important in regulating the **oxygen** -binding affinity of hemoglobin since it allosterically affects the conformation of hemoglobin leading to a decrease in **oxygen** affinity (Benesch and Benesch, Biochern. Biophys. Res. Comm., Vol. 26, p.

162, 1967). Conversely, the binding of **oxygen** allosterically reduces the affinity of hemoglobin for the polyanion. (Oxy) hemoglobin therefore binds DPG and...

...exploit the polyanion-binding specificity of hemoglobin, or indeed to perform any adjustment of its **oxygen** -binding affinity by chemically modifying the polyanion binding site, it has been necessary in the...5 difficult to maintain hemoglobin solutions in the deoxy state, (deoxy)hemoglobin, throughout a chromatographic **procedure** . Because of

these difficulties, the **technique** of affinity chromatography has not been used in the prior art to purify hemoglobin.

Hemoglobin...

...S. Pat. No. 5,296,466), during the perioperative period or during surgery in a **method** for maintaining a steady-state hemoglobin concentration in a patient (WO 95/03068), and as part of a perioperative hernodilution **procedure** used prior to surgery in an autologous blood use **method** (U.S. Pat. Nos. 5,344,393 and 5,451,205). When a patient suffers a trauma (i.e., a wound or injury) resulting, for example, from surgery, an **invasive** medical **procedure** , or an accident, the trauma disturbs the patient's horneostasis. The patient's body biologically...

...Oxy en-Affinity ofHemoglobin
, gThe major function of erythrocytes consists in the transport of molecular **oxygen** from the lungs to the peripheral tissues. The erythrocytes contain a high concentration of hemoglobin...

...partial - 5 pressure in the lung is about. 1 00 mm Hg, in the capillary **system** is about.70 mm Hg, against which 0, must be dissociated from the oxygenated hemoglobin...

...the hemoglobin-0, adduct with simultaneous conservation of the highest possible02partial pressure in the capillary **system** .

2,3-Diphosphoglycerate increases the half-saturation pressure of stripped hemoglobin at pH 7.4 fromp(**02**) (1/2)=9.3 mm Hg (37 Q, and 4.3 mm Hg (25 Q to P(**02**) (1/2)=23.7 mm Hg (37 Q, and 12.0 mm Hg (25 Q...

...21 I221) isolated from vegetal tissues. Binding of IHP to hemoglobin increases theo2halfsaturation pressure top(**02**) (1/2)=96.4 mm Hg (37 C.), andp(**02**) (1/2)=48.4 mm Hg (25 C.), respectively. IHP, like 2,3-diphosphoglycerate and other polyphosphates cannot **penetrate** the erythrocyte membrane.

Furthermore, the depletion of DPG and ATP in stored red cells leads to a progressive increase of the **oxygen** affinity of hemoglobin contained therein (Balcerzak, S. et al. (1972) Adv.

Exp. Med. Biol. 28...

...half-saturation pressure. The end point of the progressive polyphosphate depletion is defined by P(**02**) (1/2)=4.2 mm Hg, which is the half-saturation pressure of totally phosphate-free (stripped) hemoglobin; the starting point, i.e.,P(**02**) (1/2) of fresh erythrocytes, depends on the composition of the suspending medium. From these...

...solution.

Several years ago, it was discovered that the antilipidernic drug clofibric acid lowered the **oxygen** affinity of hemoglobin solutions (Abraham et al., J. Med. Chem. 25, 1015 (1982), and Abraham...

...Bezafibrate, another antilipidemic drug, was later found to be much more effective in lowering the **oxygen** affinity of hemoglobin solutions and suspensions of fresh, intact red cells (Perutz et al., Lancet...

...at stabilizing the deoxy structure of hemoglobin and shiffing the allosteric equilibrium toward the low **oxygen** affinity form (Lalezari,

Proc. Natl. Acad. Sci.

USA 85@ 6117 (1988)).

Drugs which can allosterically modify hemoglobin toward a lower **oxygen** affinity state hold potential for many clinical applications, such as for the treatment of ischernia...been considerable interest in medicine, the military health services, and the pharmaceutical industry in finding **methods** to increase **oxygen** delivery in **vivo** for ischemic insults, stroke, and trauma; to increase blood storage life; to discover radio sensitization...

...availability of either autologous blood or recombinant Hb solutions is of major interest, provided the **oxygen** affinity can be decreased to enhance **oxygen** delivery to the tissues.

2,3-Diphosphoglycerate (2,3-DPG) is the normal physiological ligand...

...is unable to pass unassisted across the erythrocyte membrane.

Enhanced Oxwen Delivea in Mamnials
The **therapy** of **oxygen** deficiencies requires the knowledge of parameters which characterize both the 0, transport capacity and the...

...0, half-saturation pressure of Hb and RBCs, and the amounts of high and low **oxygen** affinity hemoglobins in RBCs, are not routinely determined and were not given serious consideration until...
...6898) reported that the encapsulation in red blood io cells (RBCs) of IHP, via a **technique** of controlled lysis and resealing, results in a significant decrease in the hemoglobin affinity for **oxygen** . The **procedure** yielded RBCs with unchanged life spans, normal ATP and K+ levels, and normal rheological competence...

...US Patent 5,612,207) reported the use of a large-volume, continuous-flow electroporation **system** for the encapsulating IHP in human RBCs. These modified RBCs possess P50 values of approximately...

...roughly twice that of unmodified human RBCs. Additionally, 85% of the RBCs survived the electroporation **process** , displaying hematologic indices nearly identical to those of unmodified RBCs. Nicolau's electroporation **system** **processes** one unit of blood every ninety minutes.

S
Recific Clinical Applications ofEnhanced OUgen Deliverv
There are numerous clinical conditions that would benefit from treatments that would increase tissue delivery of **oxygen** bound to hemoglobin. For example, the leading cause of death in the United States today...
...myocardial infarction, stroke, intermittent claudication, and sickle cell anemia, result from an insufficient supply of **oxygen** in fluids that bathe the tissues. Likewise, the acute loss of blood following hemorrhage, traumatic injury, or surgery results in decreased **oxygen** supply to vital organs. Without **oxygen** , tissues at sites distal to the heart, and even the heart itself, cannot produce enough energy to sustain their - 8 normal functions. The result of **oxygen** deprivation is tissue death and organ failure.

Although the attention of the American public has...

...in alcohol consumption, deaths continue to occur at an alarming rate.

Since death results from **oxygen** deprivation, which in turn results in tissue destruction and/or organ dysfunction, one approach to...

...congestive heart failure.

Another condition which could benefit from an increase in the delivery of **oxygen** to the tissues is anemia. A significant portion of hospital patients experience anemia or a...

...number of heterologous transfusions and allow use of autologous transftisions in more case. The current **method** for treatment of anemia or replacement of blood loss is transfusion of whole human blood... heterologous blood.

Because IHP-treated RBCs may release up to 2-3 times as much **oxygen** as untreated red cells, in many cases, a physician will need to transfuse fewer units...

...also advantageous when the patients blood - 9 volume is excessive. In more severe cases, where **oxygen** transport is failing, the ability to improve rapidly a patient's tissue oxygenation is life saving.

Although it is evident that **methods** of enhancing **oxygen** delivery to tissues have potential medical applications, currently there are no **methods** clinically available for increasing tissue delivery of **oxygen** bound to hemoglobin. Transient, 6 to 12 hour elevations of **oxygen** deposition have been described in experimental animals using either DPG or molecules that are precursors of DPG. The natural regulation of DPG synthesis in **vivo** and its relatively short biological half-life, however, limit the DPG concentration and the duration of increased tissue P02, and thus limit its **therapeutic** usefulness.
Additionally, as reported in Genetic Engineering News, Vol. 12, No. 6, Apr. 15, 1992, several groups are attempting to engineer free **oxygen** -carrying hemoglobin as a replacement for human blood. Recombinant, genetically modified human hemoglobin that does...

...down in the body and that can readily release up to 30% of its bound **oxygen** is currently being tested by Somatogen, Inc., of Boulder Colo. While this product could be...

...surgery, it would not be effective to increase P02 levels in ischernic tissue, since its **oxygen** release capacity is equivalent to that of natural hemoglobin (2730%). As are all recombinant products, this synthetic hemoglobin is also likely to be a costly **therapeutic** .

Synthetic human hemoglobin has also been produced in neonatal pigs by injection of human genes...

...less expensive product than the Somatogen synthetic hemoglobin, but it does not solve problems with **oxygen** affinity and breakdown of hemoglobin in the body.

Summary of the Invention
The present invention relates to compositions, and **methods** of use thereof, consisting essentially of a cationic, lipophilic, water-soluble molecule (e.g., a...

...related to compounds and compositions thereof which deliver into erythrocytes allosteric modifiers of hemoglobin in **vivo** . Additionally, the invention is directed to the use of the compounds or compositions

The present invention provides a novel **method** for increasing the **oxygen** -carrying capacity of erythrocytes. In accordance with the **method** of the present invention, the IHP combines with hemoglobin in a stable way, and shifts its **oxygen** releasing capacity.

Erythrocytes with IHP-hemoglobin can release more **oxygen** per molecule than hemoglobin alone, and thus more **oxygen** is available to diffuse into tissues for each unit of blood that circulates. Injected in **vivo** , IHP is toxic and cannot be tolerated as an ordinary drug.

Another advantage of IHP...

...when stored. Normal red blood cells that have been stored do not regain their maximum **oxygen** carrying capacity in circulation for approximately 24 hours. This is because the DPG present in...

...transfusion. In contrast, red blood cells treated according to the present invention retain their maximum **oxygen** carrying capacity during storage and therefore can deliver **oxygen** to the tissues in response to demand immediately after transfusion into a human or animal...

...attack), stroke, peripheral vascular disease, intermittent 12 claudication, circulatory shock, hemorrhagic shock, anemia and chronic **hypoxia** , respiratory alkalemia, metabolic alkalosis, sickle cell anemia, reduced lung capacity caused by pneumonia, surgery, pneumonia, trauma, **chest puncture** , gangrene, anaerobic infections, blood vessel diseases such as diabetes, substitute or complement to treatment with...

...in every respect except that their P50 value is shifted towards higher partial pressures of **02** . Erythrocytes release **oxygen** only in response to demand by organs and tissue. Therefore, the compounds, compositions thereof, and **methods** of the present invention will only restore a normal level of oxygenation to healthy tissue, avoiding the cellular damage that is associated with an over-abundance of **oxygen** .

Because the compounds, compositions, and **methods** of the present invention are capable of allosterically modifying hemoglobin to favor the low **oxygen** affinity "T" state (i.e., right shifting the equilibrium curve), they will be useful in treating a variety of disease states in mammals, including humans, wherein tissues suffer from low **oxygen** tension, such as cancer and ischernia. Furthermore, as disclosed by Hirst et al. (Radiat. Res., Vol. 1 1 2, (1987), pp. 164), decreasing the **oxygen** affinity of hemoglobin in circulating blood has been shown to be beneficial in the radiotherapy...

...compounds and compositions may be administered to patients in whom the affinity of hemoglobin for **oxygen** is abnormally high. For example, certain hemoglobinopathies, certain respiratory distress syndromes, e.g., respiratory distress...

...infants aggravated by high fetal hemoglobin levels, and conditions in which the availability of hemoglobin/ **oxygen** to the tissues is decreased (e.g., in ischernic conditions such as peripheral vascular disease...

...of storage or at the time of transfusion in order to facilitate the dissociation of **oxygen** from hemoglobin and improve the **oxygen** delivering capability of the blood. When blood is stored, the hemoglobin in the blood tends to increase its affinity for **oxygen** by losing

thereof that are effective in delivering into erythrocytes allostenic modifiers of hemoglobin, lowering the **oxygen** affinity state in red blood cell suspensions and whole blood. It is an object of this invention to provides **methods** for delivering into erythrocytes allosteric modifiers of hemoglobin in whole blood and - I 0 in **vivo** , utilizing compounds or compositions thereof that do not lose their effectiveness in the presence of...

...allosteric site of hemoglobin interact with the hemoglobin molecule and impact its ability to bind **oxygen** . This invention is particularly concerned with the delivery into erythrocytes of ligands for the hemoglobin allosteric site, causing **oxygen** to be bound relatively less tightly to hemoglobin, such that **oxygen** is off-loaded from the hemoglobin molecule more easily.
The **process** of allosterically modifying hemoglobin towards a lower **oxygen** affinity state in whole blood and in **vivo** may be used in a wide variety of applications including treatments for ischernia, heart disease, wound healing, radiation **therapy** of cancer, and adult respiratory distress syndrome (ARDS). Furthermore, a decrease in the **oxygen** affinity of hemoglobin in whole blood will extend its shelf-life, or restore the **oxygen** carrying capacity of aged blood.

Brief Description of the Figures
Figure 1 presents a summary of certain experiments forming inositol hexaphosphatebisguanidiniurn cholesterol (IHP-BGTC) complexes.

Figure 2 depicts an Hb
02 dissociation curve in human RBCs after incubation with the IHP-BGTC **system** for 60 min. at room temperature [C,, = controls incubated with 1HP (I mM)DMF (3...

...IHP (2 mM)-BGTC (0.35 mM)-DMF (3%)].

Detailed Description of the Invention
The **process** of allosterically modifying hemoglobin towards a low **oxygen** affinity state in whole blood and in **vivo** could be used in a wide variety of applications including in treatments for ischernia, heart disease, wound healing, radiation **therapy** of cancer, adult respiratory distress syndrome (ARDS), etc., in extending the shelf-life of blood or restoring the **oxygen** carrying capacity of out-dated blood, and as sensitizers for x-ray irradiation in cancer **therapy** , as well as in many other applications.

This invention is related to the use of allosteric hemoglobin modifier compounds in red 3o blood cell suspensions, in whole blood, and in **vivo** . Serum albumin, which is the most abundant protein in blood plasma, has been identified as...

...a patient's blood.

This invention relates to the incorporation of a wide variety of **therapeutically** useful substances into mammalian red blood ...without unacceptable losses of R.BC contents and/or integrity. More particularly, the compounds and **methods** of the present invention makes possible the introduction or incorporation of anionic agents into R...

...slow continuous delivery or targeted delivery when the treated RBC carrier is later injected in **vivo** . The particular polyanion to be selected can be based on whether an allosteric effector of hemoglobin would be desirable for a particular treatment.

2,3-diphosphoglycerides. As described above, the compounds and compositions of this invention...

...compositions may be added to whole blood or red blood cell fractions in a closed **system** using an appropriate reservoir in which the compound or composition is placed prior to storage...

...to individual's sensitivity and the type of disease state being treated.

Solid tumors are **oxygen** deficient masses. The compounds, compositions and **methods** of this invention may be exploited to cause more **oxygen** to be delivered to tumors, increasing radical formation and thereby increasing tumor killing during radiation...

...IHP-treated blood will only be used in conjunction with radiotherapy.

The compounds, compositions and **methods** of this invention may be exploited to cause more **oxygen** to be delivered at low blood flow and low temperatures, providing the ability to decrease...

...damage, e.g., myocardial or neuronal, typically associated with these conditions.

The compounds, compositions and **methods** of this invention may be exploited to decrease the number of red blood cells required for treating hemorrhagic shock by increasing the efficiency with which they deliver **oxygen** .

Damaged tissues heal faster when there is better blood flow and increased **oxygen** tension. Therefore, the compounds, compositions and **methods** of this invention may be exploited to speed wound healing. Furthermore, by increasing **oxygen** delivery to wounded tissue, the compounds, compositions and **methods** of this invention may play a role in the destruction of infection causing bacteria at a wound.

The compounds, compositions and **methods** of this invention will be effective in 3o enhancing the delivery **oxygen** to the brain, especially before complete occlusion and reperfusion injuries occur due to free radical formation. Furthermore, the compounds, compositions and **methods** of this invention of this invention should reduce the expansion of arterioles under both hypoxic and hypotensive conditions.

The compounds, compositions and **methods** of this invention of this invention should be -14 capable of increasing loxygen delivery to blocked arteries and surrounding muscles and tissues, thereby relieving the distress of angina...

...the hyaline membrane, proliferation of collagen fibers, and swollen epithelium with increased pinocytosis.

The enhanced **oxygen** delivering capacity provided to RBCs by the compounds, compositions and **methods** of this invention can be used in the treatment and prevention of ARDS by militating against lower than normal **oxygen** delivery to the lungs.

There are several aspects of cardiac bypass surgery that make attractive the use of compounds or compositions or **methods** of the present invention. First, the compounds and compositions of the present invention act as...

...function. Up to 5% of these patients have evidence of stroke. Second, cardioplegia is the **process** of stopping the heart and protecting the heart from ischernia during heart surgery.

Cardioplegia is...

...is dissolved in blood instead of salt water. During surgery the heart is deprived of **oxygen** and the cold temperature helps slow down metabolism. Periodically during this **process** , the heart is perfused with the cardioplegia solution to wash out metabolites and 2o reactive species. Cooling the blood increases the **oxygen** affinity of its hemoglobin, thus making **oxygen** unloading less efficient. However, treatment of blood cardioplegia with compounds or compositions of the present invention will counteract the effects of cold on **oxygen** affinity and make **oxygen** release to the ischernic myocardium more efficient, possibly improving cardiac function after the heart begins to beat again. Third, during bypass surgery the patient's blood is diluted for the **process** of pump prime. This hemodilution is essentially acute anemia. Because the compounds and compositions of the present invention make **oxygen** transport more efficient, their use during hemodilution (whether in bypass surgery or other surgeries, such...

...undergoing bypass surgery require blood transfusion after surgery. The use of compounds or compositions or **methods** of the present invention to make **oxygen** transport more efficient could obviate the need for transfusion, thus decreasing the cost of surgery...

...and chemically-modified hemoglobin. Such non-naturally-occurring mutant hemoglobin is not limited by its **method** of preparation, but is typically produced using one or more of several **techniques** known in the art, including, for example, recombinant DNA technology, transgenic DNA technology, protein synthesis, and other mutation-inducing **methods** . "Chemically-modified hemoglobin" is a natural or non-natural hemoglobin molecule which is bonded to...

...moiety. For example, a hemoglobin molecule can be bonded to pyridoxal-5'-phosphate, or other **oxygen** -affinity-modifying moiety to change the **oxygen** -binding characteristics of the hemoglobin molecule, to crosslinking agents to form crosslinked or polymerized hemoglobin, or to conjugating agents to form conjugated hemoglobin.

" **Oxygen** affinity" means the strength of binding of **oxygen** to a hemoglobin molecule.

2o High **oxygen** affinity means hemoglobin does not readily release its bound **oxygen** molecules.

The P50 is a measure of **oxygen** affinity.

"Cooperativity" refers to the sigmoidal **oxygen** -binding curve of hemoglobin, i.e., the binding of the first **oxygen** to one subunit within the tetrameric hemoglobin molecule enhances the binding of **oxygen** molecules to other unligated subunits. It is conveniently measured by the Hill coefficient (n[max]). For Hb A, n[max] = 3
The term "treatment" is intended to encompass also prophylaxis, **therapy** and cure.

"Ischemia" means a temporary or prolonged lack or reduction of **oxygen** supply to an organ or skeletal tissue. Ischernia can be induced when an organ is...

...by injection, and includes, without limitation, intravenous, intramuscular, intraarterial, intrathecal, intracapsular, intraorbital, intracardiac, intradermal, intraperitoneal, **tr**anstracheal , **subcutaneous** , subcuticular, intraarticulare, subcapsular, subarachnoid, intraspinal and intrasternal injection and infusion.

As used herein, the term "surgery" refers to the treatment of diseases, injuries, and deformities by manual or operative **methods** . Common surgical **procedures** include, but are not limited to, abdominal, aural, bench, cardiac. cineplastic, conservative, cosmetic, cytoreductive, dental...

...minor, Moh's, open heart, organ transplantation, orthopedic, plastic, psychiatric, radical, reconstructive, sonic, stereotactic, structural, **thoracic** , and veterinary surgery. The **method** of the present invention is suitable for patients that are to undergo any type of...

...those described above, as well as any type of any general, major, minor, or minimal **invasive** surgery.

"Minimally **invasive** surgery" involves **puncture** or incision of the skin, or **insertion** of an instrument or foreign material into the body. Non-limiting examples of minimal **invasive** surgery include arterial or venous **catheterization** , transurethral resection, endoscopy (e.g., laparoscopy, bronchoscopy, uroscopy, pharyngoscopy, cystoscopy, hysteroscopy, gastroscopy, coloscopy, colposcopy, celioscopy...

...the dose of a drug which is lethal in 50% of test subjects.

The term " **therapeutic** index" refers to the **therapeutic** index of a drug defined as LD50/ED50The phrases "systemic administration," "administered systemically," "peripheral administration...

...administration of a compound, drug or other material other than directly into the central nervous **system** , such that it 3o enters the patient's **system** and, thus, is subject to metabolism and other like **processes** , for example, **subcutaneous** administration.
The term "structure-activity relationship (SAR)" refers to the way in which altering the...

...an atom of any element other than carbon or hydrogen. Preferred heteroatoins are boron, nitrogen, **oxygen** , phosphorus, sulftir and selenium.

The term "electron-withdrawing group" is recognized in the art, and... heteroaromatic moieties, -CF3, io CN, or the like. The term "aryl" also includes polycyclic ring **systems** having two or more cyclic rings in which two or more carbons are common to...or-X 11 RI
11
1 5 wherein X is a bond or represents an **oxygen** or a sulfur, and RI I represents a hydrogen, an alkyl, an alkenyl, -(CH2)m...

...CH2)m-R8, where in and R8 are as defined above. Where X is an **oxygen** and RI I or R'1 I is not hydrogen, the formula represents an "ester". Where X is an **oxygen** , and RI I is as defined above, the moiety is referred to herein as a...

...RI I is a hydrogen, the formula represents a "carboxylic acid". Where X is an **oxygen** , and R'1 I is hydrogen, the formula represents a

"formate". In general, where the **oxygen** atom of the above formula is replaced by sulfur, the formula represents a "thiolcarbonyl" group...

...or "alkoxy" as used herein refers to an alkyl group, as defined above, having an **oxygen** radical attached thereto. Representative alkoxyl groups include methoxy, ethoxy, propyloxy, tert-butoxy and the like. An "ether" is two hydrocarbons covalently linked by an **oxygen** . Accordingly, the substituent of an alkyl that renders that alkyl an ether is or resembles...the compound. In general, the compounds of the present invention may be prepared by the **methods** illustrated in the general reaction schemes as, for example, described below, or by modifications thereof, using readily available starting materials, reagents and conventional synthesis **procedures** . In these reactions, it is also possible to make use of variants which are in...

...novel amidinium-bearing cholesterol derivatives and pharmaceutical compositions thereof, which are particularly useful in gene **therapy** for transferring **therapeutic** genes into cells. These io compounds combine the membrane compatible features of cholesterol with the...

...Acids to Cells", and WO 96/18372, "Cationic Amphiphiles and Plasmids for Intracellular Delivery of **Therapeutic** Molecules", describe compounds, compositions and **methods** for the delivery of anions into the cytoplasm of mammalian cells, based on the use...

...Furthermore, Dietrich et al. (J. Chem. Soc., Chem. Commun. 1978, 934) have disclosed a general **method** for the introduction of guanidinium groups into macrocyclic molecules.

Synthetic "vectors", e.g., BGTC and...

...surfaces.

Several years ago, it was discovered that the antilipidemic drug clofibric acid lowered the **oxygen** affinity of hemoglobin solutions (Abraham et al., J. Med. ...Bezafibrate, another antilipidernic drug, was later found to be much more effective in lowering the **oxygen** affinity of hemoglobin solutions and suspensions of fresh, intact red cells (Perutz et al., Lancet...

...at stabilizing the deoxy structure of hemoglobin and shifting the allosteric equilibrium toward the low **oxygen** affinity form (Lalezari, Proc. Natl. Acad. Sci. USA 85, 6117 (1988)).
It has been determined...

...concentrations of effector will increase its ability to interact with hemoglobin, causing delivery of more **oxygen** .

Ligands for the allosteric site of hemoglobin include 2,3-diphosphoglycerate (DPG), inositol hexakisphosphate (IHP...

...L35 (two recently synthesized derivatives of Bzf), and pyridoxal phosphate. Additionally, hemoglobin's affinity for **oxygen** can be modulated through electrostatic interactions with chloride and/or organophosphate anions present in RBCs...

...major role in the adaptation of the respiratory properties of hemoglobin to either allometric-dependent **oxygen** needs or to various hypoxic environments.

- 28 Additionally, protons and carbon dioxide are physiological regulators for the **oxygen** affinity of hemoglobin. The heterotropic allosteric interaction between the non-heme ligands and **oxygen** , collectively called the Bohr effect, facilitates not only the transport of **oxygen** but also the exchange of carbon dioxide.
The present invention relates to compositions, and **methods** of use thereof, consisting essentially of a cationic, lipophilic, water-soluble molecule (e.g., a...

...related to compounds and compositions thereof which deliver into erythrocytes allosteric modifiers of hemoglobin in **vivo** . Additionally, the invention is directed to the use of the compounds or compositions thereof that are effective in delivering into erythrocytes allosteric modifiers of hemoglobin, lowering the **oxygen** affinity state in red blood cell suspensions and whole blood. It is an object of this invention to provides **methods** for delivering into erythrocytes allosteric modifiers of hemoglobin in whole blood and in **vivo** , utilizing compounds or compositions thereof that do not lose their effectiveness in the presence of...

...site of hemoglobin. These complexes will react with mammalian cells in vitro and/or in **vivo** to deliver their anionic component into the cytoplasm of the cells.

The guanidinium group of...a compound of the present invention is formulated for intravenous administration.
In certain embodiments, the **method** of the present invention comprises the step of administering to a subject a compound or composition of the present invention.

In certain embodiments, the **method** of the present invention comprises the step of administering to a subject a compound or composition of the present invention, wherein said administration is intravenous.

In certain embodiments, the **method** of the present invention comprises the step of administering to a subject experiencing ischernia a compound or composition of the present invention.

In certain embodiments, the **method** of the present invention comprises the step of administering to a subject experiencing ischemia a...

...or composition of the present invention, wherein said administration is intravenous.

In certain embodiments, the **method** of the present invention comprises the step of administering to a subject experiencing cardiac arrhythmia a compound or composition of the present invention.
In certain embodiments, the **method** of the present invention comprises the step of administering to a subject experiencing cardiac arrhythmia...

...or composition of the present invention, wherein said administration is intravenous.

In certain embodiments, the **method** of the present invention comprises the step of administering to a subject experiencing a heart attack a compound or composition of the present invention.

In certain embodiments, the **method** of the present invention comprises the step of administering to a subject experiencing a heart...

...or composition of the present invention, wherein said administration is intravenous.

In certain embodiments, the **method** of the present invention comprises the step of administering to a subject experiencing a stroke a compound or composition of the present invention.

In certain embodiments, the **method** of the present invention comprises the step of administering to a subject experiencing a stroke...

...composition of the present invention, wherein said administration is intravenous.

- 35 In certain embodiments, the **method** of the present invention comprises the step of administering to a subject experiencing **hypoxia** a compound or composition of the present invention.

In certain embodiments, the **method** of the present invention comprises the step of administering to a subject experiencing **hypoxia** a compound or composition of the present invention, wherein said administration is intravenous.

In certain embodiments, the **method** of the present invention comprises the step of administering to a subject afflicted with sickle cell anemia a compound or composition of the present invention.

In certain embodiments, the **method** of the present invention comprises the step of administering to a subject afflicted with sickle...

...or composition of the present invention, wherein said administration is intravenous.

In certain embodiments, the **method** of the present invention comprises the step of administering to a subject suffering from hypotension a compound or composition of the present invention.

In certain embodiments, the **method** of the present invention comprises the step of administering to a subject suffering from hypotension...

...or composition of the present invention, wherein said administration is intravenous.

In certain embodiments, the **method** of the present invention comprises the step of administering to a subject suffering from arteriosclerosis a compound or composition of the present invention.

In certain embodiments, the **method** of the present invention comprises the step of administering to a subject suffering from arteriosclerosis...

...or composition of the present invention, wherein said administration is intravenous.

In certain embodiments, the **method** of the present invention comprises the step of administering to a subject suffering from altitude sickness a compound or composition of the present invention.

In certain embodiments, the **method** of the present invention comprises the step of administering to a subject suffering from altitude...

...or composition of the present invention, wherein said administration is intravenous.

In certain embodiments, the **method** of the present invention comprises the step of adding to mammalian blood a compound or composition of the present invention.

In certain embodiments, the **method** of the present invention comprises the step of adding to plasma comprising mammalian erythrocytes a...

...Pharmaceutical Coinpositiotis
In another aspect, the present invention provides pharmaceutically acceptable compositions which comprise a **therapeutically** -effective amount of one or more of the compounds described above, formulated together with one...

...boluses, powders, granules, pastes for application to the tongue; (2) parenteral administration, for example, by **subcutaneous** , intramuscular or intravenous injection as, for example, a sterile solution or suspension; (3) topical application...

...or (4) intravaginally or intrarectally, for example, as a pessary, cream or foam.

The phrase " **therapeutically** -effective amount" as used herein means that amount of a compound, material, or composition comprising a compound of the present invention which is effective for producing some desired ltherapeutic effect in at least a sub-population of cells in an animal at a reasonable...formulations may conveniently be presented in unit dosage form and may be prepared by any **methods** well known in the art of pharmacy. For example, the amount of active ingredient which...

...a single dosage form will generally be that amount of the compound which produces a **therapeutic** effect. Generally, out of one hundred per cent, this amount will range from about I...

...70 per cent, most preferably from about IO per cent to about 30 per cent.
Methods of preparing these formulations or compositions include the step of bringing into association a compound...drug, it is desirable to slow the absorption of the drug, e.g., from a **subcutaneous** or intramuscular injection. This goal may be accomplished by the use of a liquid suspension...

...Intravenous administrations are preferred.

These compounds may be administered to humans and other animals for **therapy** by any suitable route of administration, including orally, nasally, as by, for example, a spray...pharmaceutical compositions of the present invention, are formulated into pharmaceutically-acceptable dosage forms by conventional **methods** known to those of skill in the art.

Actual dosage levels of the active ingredients...

...to obtain an amount of the active ingredient which is effective to achieve the desired **therapeutic** response for a particular patient, composition, and mode of administration, without being toxic to the...

...the pharmaceutical composition at levels lower than that required in order to achieve the desired **therapeutic** effect and gradually increase the dosage until the desired effect is achieved.

In general, a...

...be that amount of the compound which is the lowest dose effective to produce a **therapeutic** effect. Such an effective dose will generally depend upon the factors described above.

If desired...

...formulation (composition).

In another aspect, the present invention provides pharmaceutically acceptable compositions which comprise a **therapeutically** -effective amount of one or more of the subject compounds, as described above, formulated together...

...boluses, powders, granules, pastes for application to the tongue; (2) parenteral administration, for example, by **subcutaneous** , intramuscular or intravenous injection as, for example, a sterile solution or suspension; (3) topical application...

...be administered in conjunction with antimicrobial agents such as penicillins, cephalosporins, aminoglycosides and glycopeptides.

Conjunctive **therapy** , thus includes sequential, simultaneous and separate administration of the active compound in a way that the **therapeutical** effects of the first administered one is not entirely disappeared when the subsequent is administered.

Administration of the Compounds of the Present Invention
Many **techniques** currently exist for delivering drugs or other medicaments to body tissue. These include, among possible...

...directly into the blood stream.

Except for topical or transcutaneous administration, the above drug delivery **systems** tend to be systemic. In other words, administration of the drug is delivered throughout the...

...specific body lumens or passageways (i.e., blood vessels, gastrointestinal tract, urinary tract) and delivering **therapeutic** agents transmurally to specific subregions of tissue. A double-balloon **catheter** has been used to administer agents to the area confined by the balloons. A disadvantage of this **system** is that drugs may be lost through communicating vessels between the balloons. Alternatively, a **perforated** balloon has been developed to deliver agents directly into the vessel wall. A major disadvantage with both of these **systems** in certain desired applications is that the drug is delivered radially in all directions.

It...

...of pressure to enhance or otherwise control the speed of drug transport. For example, one **method** could utilize DMSO as a carrier to transport a fixative or drug through the vessel...

...dextrose solution, electrolyte solution, and saline. Generally, the liquids are administered from an intravenous delivery **system** having a container suspended above the patient, with the liquid flowing through a **catheter** hypodermic needle set to the patient.

The administration of liquids intravenously is a valuable and the patient; however, it does not always provide a satisfactory means and

method for administering concomitantly therewith a beneficial agent. Presently, a beneficial agent is often administered intravenously by (1) temporarily removing the intravenous **system** and halting the flow of liquid, and then intravenously administering the agent to the patient followed by reinserting the intravenous **system** into the patient; (2) the agent is added to the liquid in the container and...

...on a liquid containing agent for intravenously adminstering the liquid containing the agent. While these **techniques** are used, they have some disadvantages. For example, the administration of an agent through repeated **insertion** of a needle leads to unnecessary pain and trauma, they require separate connections for joining...

...of these pumps may be mounted externally to the body and are connected to a **catheter** introduced to the body of the patient. Other devices have comprised pump which is mounted **subcutaneously** to the body of the patient and which delivers a drug to the body at...

...have comprised a manually operated pump which may be mounted externally to the body or **subcutaneously** in the body of the patient whereby the pump can be activated by the patient...

...560 and, 5,085,644, and comprise devices whereby a pumping chamber is connected via **catheter** directly into the body and derives its source of drug from a holding reservoir.

Exemplification...

...at 4 C. 50 mL aliquots of the blood were centrifuged in 50 mL conical **tubes** (I 500-121 1, USA/Scientific Plastics, Ocala, FL) at 2000 x g for IO...

Claim
... wherein said second molecule is a ligand for the allosteric site of hemoglobin.

44 A **method** of enhancing **oxygen** delivery to a tissue or organ of a mammal, comprising the
step of:
administering to said mammal a composition or compound according to claim 1
or I 1.

45 A **method** of enhancing **oxygen** delivery to a tissue or organ of a mammal, comprising the step of
administering to...

...with a
composition or compound according to claim I or I 1. 3o 46. A **method** of treating a mammal afflicted with anemia, coronary infarction, pulmonary disease, congestive heart failure, myocardial infarction, stroke, peripheral vascular disease, intermittent claudication, circulatory shock, hemorrhagic shock, chronic **hypoxia** , respiratory alkalemia, metabolic alkalosis, sickle cell anemia, reduced lung capacity, gangrene, anaerobic infections, carbon monoxide...

...to said mammal a composition or compound according to claim I
or IL

47 A **method** of treating a mammal afflicted with anemia, coronary

infarction, pulmonary disease, congestive heart failure, myocardial infarction, stroke, peripheral vascular disease, intermittent claudication, circulatory shock, hemorrhagic shock, chronic **hypoxia** , respiratory alkalemia, metabolic alkalosis, sickle cell anemia, reduced lung capacity, gangrene, anaerobic infections, carbon monoxide...

...treated with a composition or compound according to claim I or I 1.

48 A **method** of improving the **oxygen** delivering capability of mammalian blood, comprising the step ofadding to said mammalian blood a composition or compound according to claim 1 or IL

49 A **method** of incorporating a **therapeutically** useful substance into mammalian red blood cells, comprising the step of: treating said mammalian red...

...compound according to claim I or 1 1, wherein said composition or compound comprises said **therapeutically** usefiil substance. - 52

Figure 1

SummaKy of Certain Experiments Forming IHP-BGTC Complexes

I 0...

26/3,K/38 (Item 38 from file: 349)
DIALOG(R)File 349:PCT FULLTEXT

00435200 **Image available**
METHOD **AND APPARATUS FOR PROVIDING VENTILATORY SUPPORT TO A PATIENT**
METHODE **PERMETTANT DE FOURNIR UNE ASSISTANCE RESPIRATOIRE A UN PATIENT ET APPAREIL CORRESPONDANT**

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SMITH Philip L,

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METHOD **AND APPARATUS FOR PROVIDING VENTILATORY SUPPORT TO A PATIENT**
METHODE **PERMETTANT DE FOURNIR UNE ASSISTANCE RESPIRATOIRE A UN PATIENT ET APPAREIL CORRESPONDANT**

Main International Patent Class: **A61M-016/04**
Fulltext Availability:
Detailed Description
Claims

English Abstract
A ventilatory support **system** which controls the flow of breathing gas to a patient (1) based on the physiological...

French Abstract
Ce **systeme** d'assistance respiratoire regulant le debit de melange respiratoire fourni a un patient (1) se...

Detailed Description

METHOD AND APPARATUS FOR PROVIDING
VENTILATORY SUPPORT TO A PATIENT
CROSS REFERENCE TO RELATED APPLICATION
This...

...herein by
reference

FIELD OF THE INVENTION
The present invention relates to a ventilatory support **system** , and more particularly relates to a **method** and apparatus for providing a controlled flow of breathing gas to a patient based on...mechanical loads include upper airway obstruction in obstructive sleep apnea, bronchial obstruction in asthma and **chronic obstructive pulmonary** disease, and reductions in lung or **chest wall** compliance in diseases involving the pulmonary parenchymal and **chest wall** . Second, ventilation may be compromised by a failure of neuromuscular mechanisms in patients who may

have disorders involving the central nervous **system** or phrenic nerves. Regardless of etiology, each of these disorders is associated with reduced
levels...

...central airways, ventilation may fall because less is required to eliminate CO2

Currently, two such **methods** are utilized clinically to aid CO, washout from the airways. In **intubated** patients, air is administered either continuously or during expiration by a **process** known as tracheal gas insufflation (TGI). Alternatively, air can be administered through a thin **transtracheal cannula** in non- **intubated** , spontaneously breathing patients. Current evidence suggests that low flow rates up
to 5 to 6...

...requirements. For CO2 washout to occur, insufflated air must vent freely to atmosphere. With continuous **transtracheal** insufflation (TTI), therefore, CO2
washout allows patients to reduce ventilation without increasing CO2

In another...own. Various mechanisms have been developed to augment ventilation with positive pressure devices, including endotracheal **tubes** , tracheostomy **tubes** and nasal/oronasal masks. In each example, a tight **seal** is required between the ventilator and the patient's airway, ... episodes and daytime somnolence. Two general approaches have been utilized to treat this disorder. First, **methods** have been devised to relieve pharyngeal airflow obstruction. At present, nasal continuous positive airway pressure...nasal mask and maintains pharyngeal patency during sleep

CPAP is most effective when a tight **seal** is maintained between the patient's airway
and the nasal mask. U.S. Patent Nos...

...side effects CPAP is often not well tolerated, and many patients do not adhere to **therapy** because the tightly applied nasal mask causes claustrophobia (Kribbs et al., Am. Rev. Respir. Dis., Vol. 147, 1993). The present invention, however, does not require such a tight **seal** . Rather than relieving upper airway obstruction as nasal CPAP, it works in concert with the...high morbidity, tracheostomy is rarely considered by either patients or physicians to be an acceptable **therapeutic** alternative, except when sleep apnea is life-threatening. The present invention avoids these adverse effects...

...and expiration that utilizes the upper airway to coordinate the pattern of
airflow

Another proposed **method** is to provide long-term **supplemental oxygen therapy** via a thin **transtracheal cannula** through which a low flow rate of **oxygen** is delivered **intratracheally** to patients with lung disease. U.S. Patent Nos. 5,181,509 and 5,090,408 disclose examples of such **cannulas** . Clinical reports and experience with this type of **cannula** has shown it to be an effective, well tolerated **oxygen** delivery **method** . However, the low flow rate of **oxygen** is not sufficient to provide satisfactory ventilatory support to patients

U.S. Patent Nos. 5,101,820 and 5,279,288 to Christopher disclose the use of a **transtracheal catheter** to provide a continuous high flow

rate of **oxygencontaining** gas to a patient. However, there are disadvantages associated with the continuous delivery of gas prior art

SUMMARY OF THE INVENTION
The present invention provides a ventilatory support **system** which controls the flow of breathing gas to a patient based on the function of ...after a delay period, or after the tracheal gas pressure falls to predetermined level. The **system** thus provides a feedback loop using tracheal pressure which reflects a patient's ventilatory and...

...patient constitute an integral part of the breathing circuit. The upper airways serve as a **valve** which controls whether the applied tracheal breathing gas inflates the ...gas to the lungs and facilitates venting of exhaled gas through the upper airways

The **system** of the present invention is useful in treating many different types of clinical disorders. For example, the **system** may be used to treat patients with upper airway obstruction, such as patients suffering from obstructive sleep apnea. The present **system** may be used to treat such patients by maintaining tracheal gas pressure above a critical...disorders, even when upper airway obstruction is absent

In a preferred embodiment, treatment with the **system** of the present invention is associated with alternate opening and with partial or complete closing...

...s tracheal pressure, the upper airway can be either open or closed to atmosphere. The **system** of the present invention controls the flow of breathing gas that it supplies to the ...state of upper airway patency An object of the present invention is to provide a **method** for giving interactive ventilatory support to a patient based on the patient's ventilatory requirements...

...the trachea of
the patient

Another object of the present invention is to provide a **method** for supplying breathing gas to a patient including the steps of **inserting** a **catheter** into the trachea of a patient, establishing a tracheal gas pressure limit for the patient, measuring gas pressure in the trachea, and controlling the flow of breathing gas through the **catheter** based on the measured gas pressure in the trachea and the properties of the upper airways. The **catheter** is preferably **inserted transtracheally** . A breathing gas flow rate value is preferably established for the patient depending upon the...apparatus for supplying breathing gas to a patient including a source of breathing gas, a **catheter** in communication with the source of breathing gas, a tracheal pressure sensor for measuring gas ...schematic illustration showing the treatment of an
obstructive sleep apnea patient with a ventilatory support **system** in accordance with
an embodiment of the present invention
FIGURE 2 is a schematic illustration...invention

FIGURE 10 is a schematic illustration of a gas delivery and tracheal pressure sensing **system** in accordance with an embodiment of the present invention

FIGURE 11 shows pressure versus airflow for flow through a 20cm long **transtracheal cannula** (1.5mm ID) and through both the **cannula** and a 14 foot

length of extension tubing (4 mm ID)

FIGURE 12 shows airflow versus pressure the combination of a **catheter** and a six foot length extension tubing (4mm ID)

FIGURE 13 shows pressure versus airflow for flow through a 11 cm long **transtracheal cannula** (4mm ID)

FIGURE 14 is a trace of tracheal pressure (PTRACH), airflow through the nose...in accordance with embodiments of the present invention

DETAILED DESCRIPTION OF THE PREFERRED EMBODIMENTS
The **method** and apparatus of the present invention provide breathing gas to a patient based on the...

...kingdom, including mammals such as humans. The term "breathing gas" as used herein means an **oxygen** -containing gas, such as air, air **supplemented** with additional **oxygen** and/or medications, substantially pure **oxygen** , and the like. The breathing gas may optionally be humidified and/or heated to approximately ...to a predetermined value. In the preferred embodiment, the flow of breathing gas is provided **transtracheally** to the
patient, and is referred to herein as **transtracheal** insufflation (TTI)

FIGURE 1 schematically illustrates a ventilatory support **system** used with a ...the patient 1 is provided with an inflow of breathing gas by means of a **catheter** 3. The **catheter** 3 includes a distal end 4 which is **inserted** through an incision 5 in the throat of the patient 1 into the trachea 2. A controller 7 is connected to the **catheter** 3 for controlling the supply of breathing gas from a breathing gas source 8. A ...controller 7. The pressure sensor 9 is located near the distal end 4 of the **catheter** 3 or, alternatively, contained within the controller 7 and connected to the trachea 2 by a **cannula** . As more fully described below, the controller 7 receives signals from the tracheal pressure sensor...

...and controls the flow of breathing gas from the breathing gas source 8 through the **catheter** 3 into the trachea 2. While a **transtracheal** **catheter** 3 is shown in FIGURE 1, and is primarily described herein, it is to be understood that other types of **catheters** may be used in accordance with the present invention, such as **catheters** **inserted** into the trachea via the upper airway of the patient. The term "trachea" is used...

...by the tracheal pressure
sensor 9, the breathing gas is either: (1) delivered through the **catheter** 3 at the established breathing gas flow rate value VIN when tracheal pressure PTRACH is...are associated with
corresponding changes in PCRITb "
When air is applied to the trachea via **transtracheal** insufflation **catheters** , it can either vent through the upper airways or fill the lungs. The distribution of...lungs will therefore depend on the biomechanical properties of both the upper airways and respiratory **system** . As shown in FIGURE 3, when the upper airways are widely patent, nearly all theThus, **transtracheal** insufflation will either augment CO2 washout, or
inflate the lungs, depending on the patency of...

...will remain closed until tracheal pressure exceeds PCRIT. When tracheal

pressure is less than PCRIT, **transtracheal** insufflation will lead to a steady rise in **intratracheal** pressure PTRACH because air cannot vent through the upper airways (VOUT = 0). This is illustrated...FIGURE 4. This rise in PTRACH will be determined by the compliance of the respiratory **system** (lungs and **chest wall** , CRS) and by the volume administered: where VIN . At represents the product of the insufflation ...and the lungs are neither inflating nor deflating. For a given level of VIN, therefore, **transtracheal** insufflation leads to progressive lung inflation without CO2 washout when PTRACH is less than PCRITb established. When a constant level of **transtracheal** insufflation is applied, therefore, the resting lung volume will increase by an amount that will...

...properties of the upper airways (PCRIT and Rs)

When PCRIT is negative, the response to **transtracheal** insufflation is analogous to the condition when PTRACH exceeds PCRIT above. With a negative PCRIT...the upper airways and
CO2 washout will occur
The influence of a constant rate of **transtracheal** insufflation in the absence of any spontaneous breathing efforts has been considered above. The foregoing...the central airways. TTI administration during expiration, therefore, helps increase CO2 washout from the respiratory **system** .From the foregoing, it is evident ...of TTI gas delivery to the lungs during inspiration and CO, washout from the respiratory **system** during expiration. Such adjustment is accomplished with two settings in accordance with the invention. First...insufflation flow VIN assists the delivery of airflow to the lungs. This pattern of intermittent **transtracheal** insufflation that is coordinated with active (spontaneous) breathing efforts is referred to herein as active **transtracheal** insufflation (ATTI).When spontaneous breathing efforts are absent, another type of intermittent flow regimen is...intermittent insufflation in the absence of spontaneous breathing efforts is referred to herein as passive **transtracheal** insufflation (PTTI) because the respiratory **system** is being
passively inflated and deflated

...the physiologic needs of a particular patient and his or her upper airway properties, the **method** and apparatus of the present invention may function in both continuous and intermittent modes, and... resistance (RS for obstructive sleep apneic patients, RUS for unobstructed non-apneic patients) and respiratory **system** compliance (T = 1/(RS CJ), and the PTRACH asymptotes at the upper airway PCRIT or... pressure limit PL,M, preferably from about 3 to about cmH2O below PLIM
Components of **transtracheal** treatment devices in accordance with preferred embodiments of the invention are schematically illustrated in FIGURES 9 and 10. For clarity, two main components of the treatment **system** are a gas
delivery **system** and a sensing **system**

The gas delivery **system** shown in FIGURE 10 is adapted to deliver, e.g., from an air/ **02** source, breathing gas flow rates of from about 4 to about 60 L/min through an extension **tube** and a **transtracheal** **cannula** . The preferred flow device which connects to the **transtracheal** **cannula** provides a constant flow at a relatively high pressure head. This pressure head would be required to overcome the high resistance of the relatively small diameter **transtracheal** **cannula** , discussed below

below

The pressure head required to drive airflow through, e.g., a 20 cm long **transtracheal cannula** (1.5 mm ID) and through both the **cannula** and a 14 foot length of extension tubing (4 mm ID) has been examined. The ...

...pressure-flow relationship when pressure is measured upstream to the 14 foot extension tubing and **transtracheal cannula** . Trials C and D represent this relationship when pressure is measured just upstream to the **transtracheal cannula** , neglecting the drop in pressure across the extension tubing. For home use at the bedside...is all that will be required. Thus, pressure-flow relationships for the combination of a **catheter** and a six foot length of extension tubing **system** have also been examined. The results appear in FIGURE 12 for airflow versus pressure. As previously noted, the extension tubing is 4mm internal diameter. A commercially available **catheter** sold under the designation SCOOP by **Transtracheal Systems** and a commercially available **cannula** sold under the designation PORTEX by Sims, Inc. were both evaluated. As can be seen required to achieve flow rates of 40-45 L/min through the PORTEX **cannula** . Such pressure heads only produce approximately 25 L/min through the SCOOP **catheter** . Therefore, a two-staged approach may be appropriate. For example, with patients who require relatively low flows of less that 25 L/min, a SCOOP-type **catheter** might suffice, whereas a larger PORTEX-type **cannula** may be selected to provided the higher flow rates. A larger bore extension tubing would also be helpful since it will allow for flow delivery through the **transtracheal cannula** at a lower pressure head. Therefore, an extension tubing ...pressures required to generate flows of up to 40 L/min through a 4mm ID **transtracheal tube** of about 11 cm in length have also been measured and the results are shown in FIGURE 13. These parameters define an exemplary minimum length and maximum diameter of the **cannula** to get the necessary air into the trachea. Thus the illustrated relationship describes the minimum...of providing, e.g., between 4 and 60 L/min through the extension tubing and **transtracheal cannula** and to that end should preferably be capable of generating pressure up to about 1,500 cmH2O. Depending on the size of the **transtracheal cannula** , the working range will likely be between 100 and 400 cmH2O

In **hypoxemic** patients, it may be desirable to blend **supplemental oxygen** into the gas stream, and the gas supply **system** can be suitably adapted to provide for selective, controlled **oxygen** blending in to the air delivered to the patient. Suitable **oxygen** blending **systems** are commercially available, e.g., Bird **Oxygen** Blender, Ohmeda Blender, and Sensor Technologies, Teledyne, Inc. Also, for purposes of safety and patient...

...desirable to fully humidify the gas stream to minimize irritation of the airway mucosa.The **transtracheal catheter** is schematically shown in FIGURE 10. The **transtracheal catheter** is an elongated flexible **tube** formed of a bio-compatible material. In accordance with the invention, the proximal end of the **catheter** preferably has a suitable connector structure for connecting the **tube** to the air supply, generally by way of an extension tubing that extends from the gas flow generating **system** to the patient. The distal end of the **tube** preferably has a plurality of **perforations** to ensure the free flow of air and is adapted for disposition in the patient's respiratory passage. The **tube** can have an

inside diameter, for example, of 1.0 mm (SCOOP) or 4.0 mm (PORTEX) for adult patients and about
half that for pediatric patients

The **tube** wall structure and thickness is such as to permit flexure of the **tube** during **insertion** into the trachea while resisting permanent deformation, kinking or collapse. The **tube** may be partly or wholly reinforced to facilitate resistance to undesired collapse and/or may have a relatively soft or compliant tip to avoid injury during **insertion** or in use. The **tube** may also be suitably coated or impregnated with a material to facilitate **insertion** and removal, to promote healing of the **insertion** site, to avoid infection and/or to maintain patency of the patient' s
airway and of the inner lumen of the **catheter**

Various **transtracheal catheters** are known and one of suitable diameter and length can be selected for incorporation in the gas delivery **system** of the invention. Exemplary **transtracheal** catheters and **methods** for **inserting** the same are disclosed in U.S. Patent Nos. 5,181,509 and 5,090,408. Nevertheless, some modifications to the conventional **transtracheal cannula** will advantageously facilitate its adaption to the treatment of sleep apnea in accordance with the invention. First, the **cannula** can have a slightly larger internal diameter to facilitate gas delivery
with lower driving pressure heads, as exemplified by the data shown in FIGURE 12. Second, the **cannula** should preferably emerge so as to sit relatively flush with the skin. This modification makes the **cannula** less obtrusive, particularly for people who wish to close their collar. Third, the **cannula** can be adapted to be removed when not used during the daytime. In that event, a **transtracheal** button component (not shown in detail) could be **inserted** to **seal** the **transtracheal** hole and prevent its closure. Various button sizes may be provided, depending on the depth of the **subcutaneous** tissues, and a soft umbrella flange may be ...a pressure transducer in the breastbone. The Medtronic product, which is incorporated in their fully **implantable** hypoglossal nerve stimulating **system** , is a flexible silicone umbrella around the end of a **cannula** . The umbrella compresses when the **cannula** is **inserted** through tissue and opens when it reaches a cavity or lumen. When the **cannula** is removed, the umbrella inverts, and it is possible for the **cannula** to be removed. Other collapsible and/or selectively anchoring structures are known, e.g, in suprapubic **catheters** , and could be provided
in accordance with the invention

A pressure release mechanism may be...

...over-inflation and its undesirable consequences

As shown in FIGURE 10, the tracheal pressure sensing **system** provided in accordance with a preferred embodiment of the invention has two principal components: a...flow generator on and off, to increase flow, or to divert the flow from the **cannula**
system , as appropriate. A data storage and retrieval **system** may also be
advantageously ...T, PCRIT, Rs, and PTRACH at VIN level) to provide feedback/data to clinicians monitoring **therapy** .The tracheal pressure sensor can advantageously be built into the **transtracheal cannula** . For example, a separate inner **cannula** can be provided with a port in the trachea. This **cannula** can then ...the pressure can be transduced

in the trachea by incorporating a piezo sensor in the **transtracheal** portion of the **cannula** . Again, a number of manufacturers produce such sensors for medical/physiologic purposes including Milar, Camtech...

...and optimally in the
range of -50 to +50 cmH2O

The tracheal pressure signal is **processed** to provide data relevant to monitoring and controlling the efficacy of the gas delivery. Detection...

...sleep including electrocardiograms, electroencephalograms, and submental electromyogram may also be advantageous. Suitable monitors and processing **systems** for such monitoring and evaluation are known, generally

EXAMPLES
Five tracheostomized patients with obstructive sleep...sleep. In addition, the tracheostomy provided direct access to the trachea for pressure
monitoring and **transtracheal** insufflation (see below)

In these patients, the tracheostomy was occluded and a thin **transtracheal** (SCOOP, **Transtracheal Systems** , Inc., Denver, CO) **cannula** was **inserted** through a tracheostomy cap through which **transtracheal** insufflation was administered at flow rates up to 45 liters/minute. Tracheal pressure was monitored with a stub adaptor **inserted** into the tracheostomy cap. Pressure in the pleural space (esophagus) outside the lungs (PES) was monitored with a standard esophageal balloon **catheter** placed perinasally in ...Patterns were developed on a test bed which included a tracheal
pressure sensor, computer, solenoid **valve** and air compressor as illustrated in FIGURE 9. The tracheal pressure PTRACH was monitored and ...

...liters/minute. Flow from the air compressor was applied either to the patient via a **transtracheal cannula** or vented directly to atmosphere by the solenoid **valve** . The solenoid was controlled by a ...respiratory responses were
assessed during periods of time as the flow rate through the tracheal **cannula** was varied randomly at levels of 0, 5.0, 7.5, 10.0, 12.5...rates of up to 40 or 50 L/min may be required to optimize the **therapy** in some patients with high ventilatory requirements, while many patients may be well treated with...20 cmH2O

From these observations, it is apparent that it should be possible to optimize **therapeutic** responses by monitoring the tracheal pressure signal. To treat apneic patients initially, higher flow rates are warranted. On the other hand, it is possible to prevent the development of excessively **intratracheal** high pressure with, for example, a tracheal pressure feedback circuit. This control feature is highly desirable to maximize **therapeutic** efficacy by reducing the number of glottic apneas, and to maximize safety by preventing pneurnothoraces... and summarized in FIGURE 29. Standard polysomnography is
performed for a patient in whom a **transtracheal cannula** has been placed. PTRACH and VOUT are also monitored continuously during sleep. PLIM is initialized...nocturnal use by the patient. This protocol is schematically illustrated in FIGURE 29

Once the **therapeutic** VIN and PLIM are established, oxyhemoglobin saturation is preferably monitored. **Supplemental oxygen** will preferably be titrated to maintain oxyhemoglobin saturation over 90

percent. At the conclusion of of inspired **oxygen** utilize during insufflation)

We noticed that we could suppress the patient's own inspiratory efforts...k is 1/T and T is the time constant for emptying of the respiratory **system** . PTRACHt - PTRACHo e + PCRIT' Our observations in four patients indicate that T is closely approximated...

...Rs b " Cr,. This finding again confirms that the inflation/deflation characteristics of the respiratory **system** under the PTTI regimen are determined by the passive biomechanical properties of the respiratory **system** and upper airways

It also ...the lungs through the upper airways despite vigorous inspiratory efforts. By providing a substantially constant **transtracheal** source of airflow, the lungs can inflate during the patient's spontaneous ...as to meet the patient's flow demand. We have also recognized periods in which **transtracheal** insufflation suppresses spontaneous inspiratory efforts completely. When this occurs, we have demonstrated the ability to...various modes are provided which support and augment ventilation by permitting lung inflation from the **transtracheal** air course and lung deflation through the upper airways

As explained hereinabove, the reported data airway is closed, **transtracheal** insufflation in accordance with the invention will expand the lungs. In patients in whom PcR...

...by providing an inflatable balloon 11 or cuff in the trachea 2 connected to a **catheter** 13 (such as a balloon on the end of a Swan Ganz **catheter**) and selectively inflating the same, as shown in phantom 12, to partially or completely block...be performed to augment ventilation or to statically elevate lung volume and washout CO, during **transtracheal** insufflation in patients with a negative PCR,T, respectively

In the alternative embodiment shown in...to deflate. Thus, intermittent electrical stimulation of the laryngeal adductor muscles can augment ventilation during **transtracheal** insufflation in patients with a negative PCRIT

Regardless of the **method** of decreasing leakage out the upper airways, inflation and deflation of the lungs will proceed...

...respiratory pump muscles, e.g., the diaphragm. This means that the work of breathing during **transtracheal** insufflation remains zero, as the patient's respiratory muscles need not contract to either inflate is therefore possible to completely unload the respiratory muscles and support/augment ventilation with **transtracheal** insufflation

While the invention has been described in connection with what is presently considered to with obstructive or restrictive lung disease, **chest wall** , neuromuscular, and neurologic diseases, and other sleep related breathing disorders. Furthermore, the present **system** may be used to treat patients under anesthesia, patients requiring full ventilatory support, patients requiring...

Claim

WHAT IS CLAIMED IS:

1. A **method** of providing interactive ventilatory support to a patient based on the physiological requirements of the patient, the **method** comprising delivering a controlled flow of breathing gas to the patient based on the gas pressure in the trachea of the patient.

2. The **method** of Claim 1, further comprising delivering the controlled flow of breathing gas **transtracheally** to the patient.

3. The **method** of Claim 1, further comprising:
establishing a tracheal gas pressure limit for the patient;
establishing...pressure in the trachea of the patient reaches the tracheal gas pressure limit.

4. The **method** of Claim 3, further comprising:
establishing a critical tracheal gas pressure level of the patient...

...establishing the tracheal gas pressure limit above the critical tracheal gas pressure level.

5. The **method** of Claim 3, further comprising resuming the flow of breathing gas after a delay period subsequent to the reduction of the flow of breathing gas.

6. The **method** of Claim 3, further comprising
establishing an expiratory target tracheal gas pressure level below the...

...in
the trachea of the patient reaches the expiratory target tracheal gas pressure.

7. The **method** of Claim 1, further comprising substantially continuously monitoring the gas pressure in the trachea.

8. A **method** of providing breathing gas to a patient comprising:
inserting a **catheter** into the trachea of a patient;
establishing a tracheal gas pressure limit for ...measuring gas pressure in the trachea; and
controlling flow of the breathing gas through the **catheter** based on the measured gas pressure in the trachea.

9. The **method** of Claim 8, further comprising **inserting** the **catheter** **transtracheally** into the trachea of the patient.

10. The **method** of Claim 8, further comprising establishing a breathing gas flow rate value for the patient.

11. The **method** of Claim 10, further comprising establishing the tracheal gas pressure limit and the breathing gas...pressure limit by a predetermined
amount if the patient experiences substantial glottic apneas.

12. The 1method of Claim 11, further comprising:
initializing the tracheal gas pressure limit at an initial value...about 2 to about 10 cmH2O if the patient experiences substantial glottic apneas.

13. The **method** of Claim 10, wherein the breathing gas flow rate value is substantially constant.

14. The **method** of Claim 10, wherein the breathing gas flow rate value is from about 4 to about 60 liters per minute.

15. The **method** of Claim 10, further comprising reducing the flow of breathing gas when the measured gas pressure in the trachea reaches the tracheal gas pressure limit.

16. The **method** of Claim 10, further comprising terminating the flow of breathing gas when the measured gas pressure in the trachea reaches the tracheal gas pressure limit.

17. The **method** of Claim 10, further comprising:
establishing a maximum tracheal gas pressure value for the patient...

...measured gas
pressure in the trachea reaches the maximum tracheal gas pressure value.

18. The **method** of Claim ...establishing the tracheal gas pressure limit above the critical tracheal gas pressure level.

19. The **method** of Claim 18, wherein the critical tracheal gas pressure level is not less than 5 cmH2O below atmospheric pressure.

20. The **method** of Claim 18, wherein this critical tracheal gas pressure level is below atmospheric pressure.

21. The **method** of Claim 20, further comprising at least partially blocking flow of gas through the upper airway of the patient.

22. The **method** of Claim 18, wherein the tracheal gas pressure limit ...from 0 to about 30 cmH2O above the critical tracheal gas pressure level

23. The **method** of Claim 18, wherein the tracheal gas pressure limit is from about 5 to about 20 cmH,O above the critical tracheal gas pressure level.

24. The **method** of Claim 10, further comprising:
reducing the flow of breathing gas when the measured gas...

...limit; and
subsequently increasing the flow of breathing gas after a delay period.

25. The **method** of Claim 24, wherein the delay period is from about 0.5 to about 10 seconds.
26. The **method** of Claim 24, further comprising:
terminating the flow of breathing gas when the measured gas...

...of breathing gas at a substantially constant
flow rate after the delay period.

27. The **method** of Claim 10, further comprising:
establishing an expiratory target tracheal gas pressure level below the pressure in the trachea reaches the expiratory target tracheal gas pressure level.

28. The **method** of Claim 27, wherein the expiratory target tracheal gas pressure is from about 2 to about 40 cmH2O below the tracheal gas pressure limit.

29. The **method** of Claim 27, further comprising:

terminating the flow of breathing gas when the measured gas...

...gas pressure in the trachea reaches the expiratory target tracheal gas pressure level.

30. The **method** of ...the differential tracheal gas pressure level above
the critical tracheal gas pressure level.

31. The **method** of Claim 10, further comprising:
substantially continuously monitoring the gas pressure in the trachea.

32. The **method** of Claim 10, further comprising:
storing information corresponding to the measured gas pressure in the trachea.

33. The **method** of Claim 10, wherein the breathing gas comprises from about 21 to 100 percent **oxygen** .

34. The **method** of Claim 10, further comprising humidifying the breathing gas.

35. The **method** of Claim ...gas to approximately the same temperature as the body temperature of th patient.

36. The **method** of Claim 10, further comprising employing the **method** on a patient suffering from obstructive sleep apnea.
37. Apparatus for providing breathing gas towherein the breathing gas delivery means comprises a **transtracheal catheter** .

39. The apparatus of Claim 38, wherein **transtracheal catheter** comprises a proximal end connected to a source of the breathing gas and a distal end for **insertion** through the trachea of the patient, and the gas pressure measuring means comprises a pressure sensor mounted on the distal end of the **catheter** .

40. The apparatus of Claim 37, wherein the flow controlling means comprises means for intermittently...Apparatus for providing breathing gas to a patient comprising:
a source of breathing gas;
a **catheter** in flow communication with the source of the .
breathing gas;
a tracheal pressure sensor for flow of the breathing gas from the source of breathing gas through the **catheter** based on the measured gas pressure in the trachea.

51. The apparatus of Claim 50, further comprising a **valve** in flow communication with the source of breathing gas and the **catheter** , and operatively coupled to the flow controller for reducing and increasing the flow of the breathing gas through the **catheter** .

52. The apparatus of Claim 50, wherein the **catheter** is a **transtracheal catheter** .
The apparatus of Claim 50, further comprising a monitor operatively coupled to the tracheal pressure...

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Set       Items   Description
S1       348512   COPD OR CHRONIC?()OBSTRUCT?()(PULMON? OR LUNG?) OR HYPOXIA?
              OR HYPOXEM? OR HYPOXAEM? OR CRICOTHRYO?
S2      2759898   OXYGEN OR 02
S3       146696   (CHEST OR THORAC? OR THORAX?)(3N)WALL? ? OR TRANS()THORA? -
             OR TRANSTHORA? OR INTRATHORA? OR INTRA()THORA? OR TRANSTRACH?
             OR INTRATRACH? OR (INTRA OR TRANS)()TRACH?
S4      1083106   CHEST? ? OR THORAC? OR THORAX?
S5      8655855   THERAPY? OR THERAPI? OR THERAPEUT? OR (FORCED OR COLLATERA-
             L?)()(VENTILAT? OR OXYGENAT?) OR SUPPLEMENT?
S6      1945633   CONDUIT? ? OR HOSE? ? OR STENT? ? OR PIPE? ? OR TUBE? ? OR
             CATHETER? OR CANNULA? OR IT02C
S7      5010517   SUBCUTAN? OR IMPLANT? OR EMPLANT? OR EMPLAC? OR IMPLAC? OR
             INSERT? OR INTUBAT? OR PUNCTUR? OR INVASIVE? OR INVIVO OR VIVO
              OR PIERC? OR PENETRAT? OR PERFORAT?
S8       220863   SEAL OR SEALS OR SEALED OR SEALING OR SEALANT OR GROMMET? -
             OR GASKET? OR (FIBRIN OR BIOCOMPATIBL?)()(GLUE? ? OR ADHESIVE?
              ?) OR (BALLOON OR FIXED)()FLANGE? ?
S9       437134   VALVE? ? OR VALVING
S10    16956061   METHOD? ?
S11    25354261   SYSTEM? ?
S12     7640830   PROCESS??
S13     3195358   PROCEDURE? ?
S14     8874627   TECHNIQUE? ?
S15        1279   S1 AND S2 AND S3:S4 AND S5:S6 AND S7
S16         528   S15 AND S2(5N)S5
S17           7   S16 AND S8:S9
S18         149   S16 AND S7(5N)S3:S4
S19          77   S16 AND S6(5N)S3:S4
S20          73   S16 AND S6(5N)S7
S21         150   S18:S20 AND S10:S14
S22          23   S18 AND S19 AND S20 AND S21
S23          41   S18 AND S19
S24          49   S19 AND S20
S25         206   S17:S24
S26         204   S25 AND PY<2004
S27         175   RD (unique items)
? show files
File 155:MEDLINE(R) 1966-2004/Apr W4
         (c) format only 2004 The Dialog Corp.
File   2:INSPEC 1969-2004/Apr W4
         (c) 2004 Institution of Electrical Engineers
File   5:Biosis Previews(R) 1969-2004/Apr W4
         (c) 2004 BIOSIS
File   6:NTIS 1964-2004/May W1
         (c) 2004 NTIS, Intl Cpyrght All Rights Res
File   8:Ei Compendex(R) 1970-2004/Apr W3
         (c) 2004 Elsevier Eng.  Info. Inc.
File  34:SciSearch(R) Cited Ref Sci 1990-2004/Apr W4
         (c) 2004 Inst for Sci Info
File 434:SciSearch(R) Cited Ref Sci 1974-1989/Dec
         (c) 1998 Inst for Sci Info
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         (c) 2004 Elsevier Science B.V.
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         (c) 2004 ProQuest Info&Learning
File  65:Inside Conferences 1993-2004/Apr W4
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File 94:JICST-EPlus 1985-2004/Apr W2
(c)2004 Japan Science and Tech Corp(JST)
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(c) 2004 FIZ TECHNIK
File 99:Wilson Appl. Sci & Tech Abs 1983-2004/Mar
(c) 2004 The HW Wilson Co.
File 481:DELPHES Eur Bus 95-2004/Apr W3
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File 583:Gale Group Globalbase(TM) 1986-2002/Dec 13
(c) 2002 The Gale Group
?

27/3,K/21 (Item 21 from file: 155)
DIALOG(R)File 155:MEDLINE(R)
(c) format only 2004 The Dialog Corp. All rts. reserv.

13111664 PMID: 8775745
Complications in the use of the subcutaneous **tunnelled** intratracheal oxygen catheter .
in't Veen J C; Stolk J; Dijkman J H
Department of Pulmonology, University Hospital, Leiden, Netherlands.
Netherlands journal of medicine (NETHERLANDS) Jan **1996** , 48 (1) p8-10, ISSN 0300-2977 Journal Code: 0356133
Document type: Case Reports; Journal Article
Languages: ENGLISH
Main Citation Owner: NLM
Record type: Completed

Complications in the use of the subcutaneous **tunnelled** intratracheal oxygen catheter .
Jan **1996** ,
Transtracheal oxygen delivery seems to be a safe **procedure** in the treatment of **chronic obstructive pulmonary** disease (**COPD**) with chronic **hypoxaemia** . Even so, serious complications do occur. Three patients in whom we used a **subcutaneous** tunnelled **intratracheal oxygen catheter** (ITO2C) are described. Surgical intervention was required in all because of complications from the **procedure** . One of the complications--tracheal and **catheter** obstruction with stridor and **subcutaneous** emphysema by granulomatous tissue--has to our knowledge not been reported before.
Descriptors: **Intubation** , **Intratracheal** --adverse effects--AE; * **Oxygen** Inhalation **Therapy** --instrumentation--IS; Aged; Airway Obstruction --etiology--ET; Equipment Failure; Granuloma, Foreign-Body--etiology--ET; **Intubation** , **Intratracheal** --instrumentation--IS; Lung Diseases, Obstructive-- **therapy** --TH; Respiratory Sounds--etiology--ET; **Subcutaneous** Emphysema--etiology--ET; Trachea

27/3,K/72 (Item 72 from file: 155)
DIALOG(R)File 155:MEDLINE(R)

08100666 PMID: 2495902
The micro-trach. A seven-year experience with transtracheal oxygen therapy .
Heimlich H J; Carr G C
Heimlich Institute at Xavier University, Cincinnati 45207-1096.
Chest (UNITED STATES) May **1989** , 95 (5) p1008-12, ISSN 0012-3692
Journal Code: 0231335
Document type: Journal Article
Languages: ENGLISH
Main Citation Owner: NLM
Record type: Completed

The micro-trach. A seven-year experience with transtracheal oxygen therapy .
May **1989** ,
Over a six-year period, 200 patients requiring long-term **oxygen therapy** for **hypoxemic** lung disease underwent **insertion** of the micro-trach **transtracheal catheter** and were evaluated for one to seven years. The **catheter** requires no removal for cleaning; it is designed to function undisturbed within the trachea for six months between replacements. **Transtracheal oxygen** delivery and saline instillation were instituted immediately after **inserting** the device. **Oxygen** administration at a rate of 0.25 to 3 L/min was equivalent to 1...

... had dropped out of the study. Most patients comply with prescribed 24-hour-a-day **oxygen** use; in keeping with the NOTT study, life expectancy of emphysema patients may therefore be...
Descriptors: **Catheters** , Indwelling; * **Intubation** , **Intratracheal** ; * **Oxygen** Inhalation **Therapy** --instrumentation--IS; Adult; Aged; Carbon Dioxide--blood--BL; Dyspnea-- **therapy** --TH; Equipment Design; Lung Diseases, Obstructive-- **therapy** --TH; Middle Aged; **Oxygen** --blood--BL; Patient Compliance; Pneumoconiosis-- **therapy** --TH; Pulmonary Fibrosis-- **therapy** --TH
Chemical Name: Carbon Dioxide; **Oxygen**

27/3,K/84 (Item 84 from file: 155)
DIALOG(R)File 155:MEDLINE(R)

06935873 PMID: 4051407
Transtracheal catheter technique **for pulmonary rehabilitation.**
Heimlich H J; Carr G C
Annals of otology, rhinology, and laryngology (UNITED STATES) Sep-Oct **1985** , 94 (5 Pt 1) p502-4, ISSN 0003-4894 Journal Code: 0407300
Document type: Journal Article
Languages: ENGLISH
Main Citation Owner: NLM
Record type: Completed

Transtracheal catheter technique **for pulmonary rehabilitation.**
Sep-Oct **1985** ,
In over 100 **chronic obstructive pulmonary** disease patients, continuous **oxygen therapy** has been provided for up to 4 years using Micro-Trach percutaneous **transtracheal catheters** less than 2.0 mm in diameter. Successful rehabilitation has been achieved. Advances in materials, **insertion technique** , and protocols have simplified patient management. Complications occasionally encountered are bleeding, infection, **subcutaneous** emphysema, increased mucus production, and **catheter** failure or displacement. Long-term delivery of **supplemental oxygen** directly into the tracheobronchial tree eliminates the **oxygen** loss through the oral and nasal orifices that occurs when a nasal **cannula** is used. This closed **system** permits maintenance of **therapeutic** arterial blood levels with improved efficiency, greater comfort, and increased activity. The elimination of nasal irritation and cosmetic objections caused by nasal **cannulas** increases patient compliance, resulting in uninterrupted 24-hour-a-day **oxygen** use as indicated. The **technique** of **inserting** a **transtracheal catheter** and postinsertion management are discussed in detail.
Descriptors: Lung Diseases, Obstructive--rehabilitation--RH; * **Oxygen** Inhalation **Therapy** -- **methods** --MT; Adult; Aged; **Catheterization** --instrumentation--IS; **Catheterization** -- **methods** --MT; Middle Aged; **Oxygen** Inhalation **Therapy** --adverse effects--AE; Patient Compliance; Pulmonary Fibrosis--rehabilitation--RH

27/3,K/88 (Item 88 from file: 155)
DIALOG(R)File 155:MEDLINE(R)

06006192 PMID: 7149552
Respiratory rehabilitation with transtracheal oxygen system .
Heimlich H J
Annals of otology, rhinology, and laryngology (UNITED STATES) Nov-Dec **1982** , 91 (6 Pt 1) p643-7, ISSN 0003-4894 Journal Code: 0407300
Document type: Case Reports; Journal Article
Languages: ENGLISH
Main Citation Owner: NLM
Record type: Completed

Respiratory rehabilitation with transtracheal oxygen system .
Nov-Dec **1982** ,
A **system** of **transtracheal oxygen** administration has been developed which is more effective for rehabilitating **chronic obstructive pulmonary** disease (**COPD**) patients than traditional **systems** for providing continuous **oxygen therapy** . The procedure involves administering **oxygen** continuously through a No. 16 intravenous **catheter inserted transtracheally** . **Therapeutic** PaO2 levels are attained with an **oxygen** flow of 0.25 to 1 liter per minute. **Transtracheal oxygen** administration has numerous advantages over nasal **cannula** or Venturi mask devices. With this **system** , the patient requires 3 to 4 times less **oxygen** ; therefore, a 2.7-kg (6-lb) portable tank will last most of one day. **Oxygen** -enriched air via **transtracheal catheter** reaches the lungs directly with less respiratory effort. Delivery of **oxygen** is not impaired by sinusitis, mouth-breathing, displacement of nasal **cannula** or loss of **oxygen** into the room. Patients experience an immediate sensation of being able to breathe more easily, begin ambulating the day of the **procedure** , have improved nutrition and return to many normal activities.
Descriptors: Lung Diseases, Obstructive--rehabilitation--RH; *Respiratory **Therapy** -- **methods** --MT; Adult; Aged; Animals; **Catheterization** ; Dogs; Middle Aged; Respiratory **Therapy** --economics--EC; Respiratory **Therapy** --instrumentation--IS

27/3,K/110 (Item 4 from file: 5)
DIALOG(R)File 5:Biosis Previews(R)

0010267845 BIOSIS NO.: 199698735678
Complications in the use of the subcutaneous **tunnelled** intratracheal oxygen catheter
AUTHOR: In 'T Veen J C C M (Reprint); Stolk J; Dijkman J H
AUTHOR ADDRESS: Dep. Pulmonol., Univ. Hosp., Rijnsburgerweg 10, 2333 AA Leiden, Netherlands**Netherlands
JOURNAL: Netherlands Journal of Medicine 48 (1): p8-10 1996 **1996**
ISSN: 0300-2977
DOCUMENT TYPE: Article
RECORD TYPE: Abstract
LANGUAGE: English

Complications in the use of the subcutaneous **tunnelled** intratracheal oxygen catheter
1996

ABSTRACT: **Transtracheal oxygen** delivery seems to be a safe **procedure** in the treatment of **chronic obstructive pulmonary** disease (**COPD**) with chronic **hypoxaemia** . Even so, serious complications do occur. Three patients in whom we used a **subcutaneous** tunnelled **intratracheal oxygen catheter** (ITO-2C) are described. Surgical intervention was required in all because of complications from the **procedure** . One of the complications-tracheal and **catheter** obstruction with stridor and **subcutaneous** emphysema by granulomatous tissue-has to our knowledge not been reported before.
...REGISTRY NUMBERS: **OXYGEN**
DESCRIPTORS:
MAJOR CONCEPTS: **Methods** and **Techniques** ;
CHEMICALS & BIOCHEMICALS: **OXYGEN**
MISCELLANEOUS TERMS: ... **CATHETER** OBSTRUCTION...

... **CHRONIC OBSTRUCTIVE PULMONARY** DISEASE...

... **HYPOXIA** ; ...

... **TRANSTRACHEAL OXYGEN THERAPY**

27/3,K/145 (Item 18 from file: 73)
DIALOG(R)File 73:EMBASE

07353674 EMBASE No: 1998260998
Long-term clinical experience with transtracheal oxygen catheters
Orvidas L.J.; Kasperbauer J.L.; Staats B.A.; Olsen K.D.
Dr. L.J. Orvidas, Department of Otorhinolaryngology, Mayo Clinic Rochester, 200 First Street SW, Rochester, MN 55905 United States
Mayo Clinic Proceedings (MAYO CLIN. PROC.) (United States) 1998, 73/8 (739-744)
CODEN: MACPA ISSN: 0025-6196
DOCUMENT TYPE: Journal; Article
LANGUAGE: ENGLISH SUMMARY LANGUAGE: ENGLISH
NUMBER OF REFERENCES: 33

Long-term clinical experience with transtracheal oxygen catheters

Objective: To evaluate and discuss the use of **transtracheal oxygen catheters** for the treatment of chronic **hypoxemia** and to discuss the complications associated with the placement and care of these devices. Design...

...a retrospective study at a tertiary medical center and reviewed the pertinent literature. Material and **Methods** : The medical records of 56 patients who received a **transtracheal oxygen catheter** between January 1987 and June 1992 at our institution were reviewed for demographic data, diagnosis leading to **catheter** placement, complications related to **catheter** use, reason for **catheter** removal, and duration of use. Follow-up results were established by documentation in the medical...

...or telephone interview. Results: During the study period, 39 men and 17 women received a **transtracheal catheter** . More than half the patients (52%) had **chronic obstructive pulmonary** disease. The duration of use of the **catheter** ranged from 2 days to more than 6 years, and the most frequent cause for removal of the **catheter** was death. Of the 56 patients, 42 died with the **catheter** in place, 24 within the first year after placement. Complications ranged from mucous plugging (38% of patients) to pneumothorax (4%), and no patient died of a **catheter** -related complication. Overall, 55% of patients had their **catheter** for less than 1 year after placement. Conclusion: In patients with **transtracheal oxygen catheters** , problems related to mucous plugging are common, but severe complications such as pneumothorax and pneumomediastinum are uncommon. Although selection factors that would identify ideal candidates for **transtracheal oxygen therapy** have not been established, such a **catheter** is best placed in highly motivated patients who can physically manage the daily care of...
MEDICAL DESCRIPTORS:
*endotracheal **intubation** ; * **oxygen therapy** **catheterization** ; device; pneumothorax--complication--co; pneumomediastinum--complication--co; lung ventilation; **chronic obstructive lung** disease-- **therapy** --th; **cannulation** ; lung minute volume; human; male; female; major clinical study; aged; adult; article **1998**

27/3,K/159 (Item 32 from file: 73)
DIALOG(R)File 73:EMBASE

04296989 EMBASE No: 1990179545
Transtracheal oxygen therapy **for respiratory insufficiency**
TRANSTRACHEALE SAUERSTOFF-LANGZEITTHERAPIE BEI RESPIRATORISCHER INSUFFIZIENZ
Wurtemberger G.; Matthys H.
Medizinische Universitatskl., Abteilung Pneumologie, Hugstetter Str. 55,D-7800 Freiburg Germany
Pneumologie, Sonderheft (PNEUMOLOGIE SONDERH.) (Germany) 1990, 44/1 (191-192)
CODEN: PNSOE ISSN: 0934-8573
DOCUMENT TYPE: Journal; Conference Paper
LANGUAGE: GERMAN SUMMARY LANGUAGE: ENGLISH

Transtracheal oxygen therapy **for respiratory insufficiency**
TRANSTRACHEALE SAUERSTOFF-LANGZEITTHERAPIE BEI RESPIRATORISCHER INSUFFIZIENZ

The benefit of long-term **oxygen therapy** for patients under refractory **hypoxaemia** has been proven. Dealing with side effects due to high **oxygen** flow rates for sufficient oxygenation we treated four patients via a **transtracheal oxygen catheter** . Data are shown. Refractory **hypoxaemia** was successfully treated requiring 50% less **oxygen** . There were no complications related to the **insertion procedure** . Increased mucous plugging, while acute bacterial infection was observed, required frequent instillation of 0,5 cc normal saline. All patients experience an improvement in their quality of life with **transtracheal oxygen** .
MEDICAL DESCRIPTORS:
* **oxygen therapy** ; *respiratory failure-- **therapy** --th
adult; **hypoxia** ; quality of life; case report; human; methodology; female; conference paper; priority journal
SECTION HEADINGS:
006 Internal Medicine
015 **Chest** Diseases, **Thoracic** Surgery and Tuberculosis
027 Biophysics, Bioengineering and Medical Instrumentation
1990

27/3,K/163 (Item 36 from file: 73)
DIALOG(R)File 73:EMBASE

02600841 EMBASE No: 1984219799
Oxygen therapy **by** transtracheal catheter **for patients with chronic respiratory failure and** hypoxia
SONDE **TRANSTRACHEALE** A DEMEURE POUR ADMINISTRATION D'OXYGENE CHEZ L'INSUFFISANT RESPIRATOIRE CHRONIQUE HYPOXIQUE
Bugnas B.; Lemoigne F.; Ferrari Ch.; Blaive B.
Service de Pneumologie, Hopital Pasteur, F 06031 Nice France
Presse Medicale (PRESSE MED.) (France) 1984, 13/36 (2207-2208)
CODEN: PRMEE
DOCUMENT TYPE: Journal
LANGUAGE: FRENCH SUMMARY LANGUAGE: ENGLISH

Oxygen therapy **by** transtracheal catheter **for patients with chronic respiratory failure and** hypoxia
SONDE **TRANSTRACHEALE** A DEMEURE POUR ADMINISTRATION D'OXYGENE CHEZ L'INSUFFISANT RESPIRATOIRE CHRONIQUE HYPOXIQUE

A new **technique** for administering **oxygen** to patients with severe chronic respiratory failure is reported. It consists of introducing a **catheter** , 2 mm in diameter, into the trachea between the second and third tracheal rings under local anasthesia. The **technique** was used in a 70-year old patient with severe **chronic obstructive lung** disease and resulted in significant reduction of dyspnoea, improvement in general condition with a weight gain of 6 kg in 6 months, and a 15 mmHg increase in arterial partial **oxygen** pressure for the same **oxygen** flow rate. This **technique** appears to be indicated for patients with chronic respiratory failure whenever dyspnoea is not adequately reduced by **oxygen** given through a nasal **tube** .
DRUG DESCRIPTORS:
* **oxygen**
MEDICAL DESCRIPTORS:
endotracheal **intubation** ; methodology; **therapy** ; case report; human; respiratory **system**
CAS REGISTRY NO.: 7782-44-7 (**oxygen**)
SECTION HEADINGS:
015 **Chest** Diseases, **Thoracic** Surgery and Tuberculosis
1984

```
Set       Items   Description
S1        23593   COPD OR CHRONIC?()OBSTRUCT?()(PULMON? OR LUNG?) OR HYPOXIA?
             OR HYPOXEM? OR HYPOXAEM? OR CRICOTHRYO?
S2       726944   OXYGEN OR 02
S3         7555   (CHEST OR THORAC? OR THORAX?)(3N)WALL? ? OR TRANS()THORA? -
           OR TRANSTHORA? OR INTRATHORA? OR INTRA()THORA? OR TRANSTRACH?
           OR INTRATRACH? OR (INTRA OR TRANS)()TRACH?
S4       110894   CHEST? ? OR THORAC? OR THORAX?
S5      1252710   THERAPY? OR THERAPI? OR THERAPEUT? OR (FORCED OR COLLATERA-
           L?)()(VENTILAT? OR OXYGENAT?) OR SUPPLEMENT?
S6       660299   CONDUIT? ? OR HOSE? ? OR STENT? ? OR PIPE? ? OR TUBE? ? OR
           CATHETER? OR CANNULA? OR IT02C
S7       940105   SUBCUTAN? OR IMPLANT? OR EMPLANT? OR EMPLAC? OR IMPLAC? OR
           INSERT? OR INTUBAT? OR PUNCTUR? OR INVASIVE? OR INVIVO OR VIVO
            OR PIERC? OR PENETRAT? OR PERFORAT?
S8       287341   SEAL OR SEALS OR SEALED OR SEALING OR SEALANT OR GROMMET? -
           OR GASKET? OR (FIBRIN OR BIOCOMPATIBL?)()(GLUE? ? OR ADHESIVE?
            ?) OR (BALLOON OR FIXED)()FLANGE? ?
S9        155202   VALVE? ? OR VALVING
S10      1369125   METHOD? ?
S11      8277872   SYSTEM? ?
S12      4016398   PROCESS??
S13      1606798   PROCEDURE? ?
S14      1010037   TECHNIQUE? ?
S15          685   S1 AND S2(5N)S5 AND S3:S4 AND S6 AND S7
S16          244   S15 AND S8:S9
S17          685   S15:S16
S18          669   S17 AND S10:S14
S19          685   S17:S18
S20          127   S19 AND S7(5N)S3:S4
S21          192   S19 AND S6(5N)S3:S4
S22           86   S20 AND S21
S23           84   S22 AND PY<2004
S24           76   RD (unique items)
? show files
File  16:Gale Group PROMT(R) 1990-2004/May 03
         (c) 2004 The Gale Group
File 160:Gale Group PROMT(R) 1972-1989
         (c) 1999 The Gale Group
File 148:Gale Group Trade & Industry DB 1976-2004/May 03
         (c)2004 The Gale Group
File 149:TGG Health&Wellness DB(SM) 1976-2004/APR W4
         (c) 2004 The Gale Group
File 621:Gale Group New Prod.Annou.(R) 1985-2004/Apr 30
         (c) 2004 The Gale Group
File 444:New England Journal of Med. 1985-2004/May W1
         (c) 2004 Mass. Med. Soc.
File 441:ESPICOM Pharm&Med DEVICE NEWS 2004/Apr W4
         (c) 2004 ESPICOM Bus.Intell.
File 369:New Scientist 1994-2004/Apr W4
         (c) 2004 Reed Business Information Ltd.
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         (c) 1999 AAAS
File 129:PHIND(Archival) 1980-2004/Apr W4
         (c) 2004 PJB Publications, Ltd.
File 130:PHIND(Daily & Current) 2004/Apr 30
         (c) 2004 PJB Publications,Ltd.
File 135:NewsRx Weekly Reports 1995-2004/Apr W4
         (c) 2004 NewsRx
File  98:General Sci Abs/Full-Text 1984-2004/Apr
         (c) 2004 The HW Wilson Co.
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File 15:ABI/Inform(R) 1971-2004/May 01
(c) 2004 ProQuest Info&Learning
?

24/3,K/8 (Item 8 from file: 148)
DIALOG(R)File 148:Gale Group Trade & Industry DB

04130394 SUPPLIER NUMBER: 07918991 (USE FORMAT 7 OR 9 FOR FULL TEXT)
A better way to deliver long-term oxygen therapy .
Grandstrom, Diane; Wierzbicki, Linda A.
RN, v52, n9, p58(7)
Sept, 1989
ISSN: 0033-7021 LANGUAGE: ENGLISH RECORD TYPE: FULLTEXT
WORD COUNT: 2135 LINE COUNT: 00168

A better way to deliver long-term oxygen therapy .

TEXT:
An efficient new **method** eliminates the nasal **cannula** and improves the patient's quality of life.
... patients may avoid the therapy simply because they don't like the way the nasal **cannula** looks or because it gets in their way. Worn 24 hours a day, the plastic...

...tracheostomy was the only option available for patients who needed continuous long-term therapy. Now **transtracheal** oxygenation (TTO sub 2) offers a more comfortable and acceptable alternative.
The advantages of **transtracheal** O sub 2
The principle behind this **method** is similiar to that of a tracheostomyoxygen is delivered to the lungs through a **tube inserted** into the trachea. Unlike the large, rigid tracheostomy **tube** , however, the **transtracheal catheter** is small and flexible, and doesn't interfere with the cough reflex or speech.
Transtracheal oxygenation has advantages over the nasal **cannula** , too. Some of the oxygen delivered by **cannula** escapes through the nose and mouth. Because the **catheter** bypasses these areas, **transtracheal** delivery is more efficient: A patient's **supplemental oxygen** requirement is often-less than half what's needed with a nasal **cannula** . That not only saves money but also gives the patient greater mobility since portable supplies...

...the mucous membranes. The patient's sense of taste and smell improve, increasing appetite.
The **transtracheal system** is also less conspicuous than a nasal **cannula** . The external part of the **catheter** lies flush with the skin below the collar. A stainless steel beadchain threaded through a...

...as a shoulder bag.
Since there's no tubing around the head and face, the **transtracheal method** doesn't interfere with eating, shaving, applying makeup, or kissing. With all of these advantages...

...patients are candidates for TTO sub 2
Most patients who need continuous therapy can consider **transtracheal** oxygenation, but clinicians generally recommend that a patient use the nasal **cannula** for at least a month before making an informed decision.
Cost is a factor. Although...

...Medicare reimbursement is discussed in detail in July's article on the basics of home **oxygen therapy** , "Good nursing gets **COPD** patients out of hospitals.") In addition, the patient or a family member must be willing and able to assume responsibility for **catheter** care.
As for clinical criteria, standard pre- **procedure** screening includes

a CBC and ABGs to document the need for continuous **therapy** and provide baseline data for **oxygen** requirements.

Spirometry findings and **chest** X-ray eliminate some candidates. **Transtracheal** oxygenation is also contraindicated for patients with disabling anxiety, acute respiratory failure, or pleural herniation at the proposed **insertion** site.

Some patients who pass standard screening are still less than ideal candidates because of...

...and skills needed for a smooth transition to TT0 sub 2.

Making the switch to **transtracheal** O sub 2

Inserting the **transtracheal catheter** is a simple **procedure** . If it's done as outpatient surgery, however, the patient must make arrangements for the ride home afterward.

All patients must fast for six to eight hours before the **procedure** . A sedative is given an hour ahead of time. Tbe patient may also receive a ...

...1.0% lidocaine (Xylocaine), a local anesthetic, is injected into the trachea just before the **procedure** .

Patients with bronchospasm may also receive an aerosol bronchodilator or an injection of atropine. A pulse oximeter and EKG leads are applied, and **supplemental oxygen** is administered by nasal **cannula** .

During the **procedure** the patient will either sit in a chair that has a headrest or lie on...

...back with a pillow under his shoulders. The doctor extends the neck and selects the **insertion** site, which is cleaned with an antimicrobial solution and injected with a local anesthetic.

The next step depends on whether the physician uses a Heimlich Micro-Trach or a SCOOP **catheter** . The Micro-Trach (designed by Dr. Henry Heimlich, who developed **transtracheal** oxygenation in 1980) is **inserted** over a removable needle and guide wire after the physician makes a small **puncture** wound with the needle.

The SCOOP (Spofford Christopher Oxygen Optimizing Prosthesis, a **catheter** that was developed by Drs. Bryan Spofford and Kent Christopher) also uses a needle and guide wire, but is longer and larger than the Micro-Trach. **Insertion** therefore requires a small incision.

No matter which **cathe**ter is used the patient has a **chest** X-ray after the **procedure** to check position and rule out pneumothorax.

During the first two to three hours after **insertion** assess the patient frequently for respiratory distress, **catheter** displacement, and excessive bleeding-indicated by more than a few drops of blood around the **insertion** site or large amounts of blood-streaked sputum. Monitor ABGs and pulse oximetry readings for...

...of pain, coughing, and hoarseness. Give acetaminophen (Tylenol) as ordered for mild pain at the **catheter** site. Report severe or worsening pain immediately. ...patient that hoarseness will clear as the anesthesia wears off.

The switch from nasal to **transtracheal** oxygen depends on which **catheter** is used. Delivery via the Micro-Trach can begin immediately after **insertion** , but some hospital protocols call for waiting a week to let the wound heal. This decreases the incidence of **subcutaneous** emphysema-air leaking into the tissues around the **catheter** site.

A one-week delay is standard with the SCOOP **catheter** . The preliminary **catheter** , not designed for oxygen delivery, is left in place for a week until the opening...

...to mature. It's then replaced by the SCOOP 1. Oxygen is administered

through this **catheter** , which remains in place for six to eight weeks until the tract matures fully. At...

...with the SCOOP 2. You'll find pictures of the Heimlich Micro-Trach and SCOOP **catheters** and a chart comparing them on page 60.

Going home with TTO sub 2

Potential complications of transtra cheal **catheter** **insertion** include i fection, bronchospasm, bleeding pneumothorax, respiratory failure: and **subcutaneous** emphysema. Review the signs and symptoms of these problems with the patient before discharge. Give...

...on an index card or in the patient workbook that's provided with the SCOOP **catheter** .

Warn the patient to call his doctor right away about any of the following: a...

...swelling of the neck or face, increased sputum production, severe pain or bleeding around the **catheter** site, cyanosis of the lips or fingers, or worsening anxiety.

Show the patient how to...

...his temperature orally. He should do this twice a day for a week after the **procedure** . A fever of more than 99.50 deg. F (37.5 deg. C) warrants a ...

...for the equipment he'll need at home. When the patient changes from nasal to **transtracheal** oxygen, he'll adjust the flow rate according to pulse oximetry readings. He'll need...

...care visit for ABGs to confirm adequate ventilation and oxygenation. Patients who use the SCOOP **system** will need to schedule at least two visits for **catheter** changes.

The home care provider may have to adjust equipment. A patient may not need...

...MicroTrach can increase resistance to flow. That, in turn, increases pressure in the oxygen regulatory **system** and activates the release **valve** on the humidifier. A respiratory therapist can deactivate the **valve** without affecting oxygen delivery or endangering the patient. Key points in **catheter** care

The patient will have to learn how to care for the **catheter** and skin around it, He'll clean the area with a cotton swab and water...

...skin creams or ointments unless instructed to do so by the physician.

The steps for **catheter** care are specific for each type. Oxygen flow and the absence of side holes make...

...so, the patient must instill 0.5 to 1ml of sterile normal saline into the **catheter** two or three times a day. The saline stimulates a cough, clearing the lungs of...

...vigorous cough can dislodge the MicroTrach. If that happens, the patient should simply swab the **catheter** with alcohol and reinsert it. If be has trouble repositioning tbe **catheter** , he should switch to nasal oxygen and call his physician.

SCOOPs are cleaned at least...

...and a special rod. During this phase, mucus can accumulate at the tip of the **catheter** . Suspect this problem if the patient complains of sudden dyspnea, cough, or wheezing. Removing the **catheter** over a guide wire and reinserting it will clear the mucus, but this should be attempted only by a

physician, nurse, or respiratory therapist who is familiar with the **technique** .

Once the tract is mature and oxygen flow established, the SCOOP 1 and 2 can be changed easily: The patient removes tbe soiled **catheter** and **inserts** a clean one. He washes the dirty **catheter** with the special cleaning rod and an antibacterial soap and water and stores it in a clean, dry place away from direct sunlight. Caution against changing the **catheter** more than twice a day-once in the morning and then again at night. Frequent...

...and may also lead to sear tissue formation.

Additional cleanings should be done with the **catheter** in place. Remind the patient that he must replace these **catheters** every three months.

According to Dr. Heimlich, the Micro-Trach is usually changed about every...way they feel and what they can achieve-and that's the greatest accomplishment of **transtracheal** therapy.

CAPTIONS:. Comparing the Heimlich Micro-Trach and SCOOP **catheters** . (chart)

DESCRIPTORS: **Oxygen therapy --... ... Catheters --**
19890900

24/3,K/32 (Item 21 from file: 149)
DIALOG(R)File 149:TGG Health&Wellness DB(SM)

01773232 SUPPLIER NUMBER: 20573379 (USE FORMAT 7 OR 9 FOR FULL TEXT)
Rapidly progressive extensive subcutaneous **emphysema associated with an** implantable intratracheal **oxygen** catheter .
Blackmon, Griffith M.; Johnson, Martin C., II; Plotkin, Elizabeth
Chest, v113, n3, p834(3)
March,
1998
PUBLICATION FORMAT: Magazine/Journal; Refereed ISSN: 0012-3692
LANGUAGE: English RECORD TYPE: Fulltext TARGET AUDIENCE: Professional
WORD COUNT: 1653 LINE COUNT: 00149

1Rapidly progressive extensive subcutaneous **emphysema associated with an** implantable intratracheal **oxygen** catheter .

TEXT:

Localized **subcutaneous** emphysema is a recognized complication of **transtracheal** oxygen **catheters** . It usually occurs in the immediate postoperative period or in association with **catheter** tip migration. This is a case of rapidly progressive, extensive **subcutaneous** emphysema apparently resulting from paroxysms of coughing in a patient with a normally functioning **implanted intratracheal** oxygen **catheter** several weeks after placement. (**CHEST** 1998; 113:834-36)

Key words: obstructive lung disease; **oxygen** inhalation **therapy** ; **subcutaneous** emphysema

Long-term continuous **oxygen therapy** improves survival in **hypoxemic** patients with **COPD** .(1,2) However, conventional domiciliary **oxygen therapy** via nasal prongs may limit patient mobility and be uncomfortable or cosmetically unacceptable for some patients. Oxygen concentrators and compressed oxygen cylinders are relatively immobile, and portable liquid oxygen **systems** may be rapidly exhausted at high flow rates. **Transtracheal** oxygen **catheters** overcome many of these limitations.(3-6) oxygen flow requirements of nasal prongs may be decreased by 50% with **transtracheal** gas delivery. The increased efficiency is presumably due primarily to reduced anatomic dead space and...

...in the neck may be concealed under clothing. Although generally well tolerated, complications include perioperative **subcutaneous** emphysema, localized wound infection, **catheter** dislodgement and fracture, and formation of mucus plugs on the **catheter** tip which may occlude the tracheal lumen.(4,5,7) **Implanted intratracheal catheters** are cosmetically superior since the device is not visible at the neck, does not require...
...less susceptible, although not immune, to infection, migration, and mucus plug formation.(8-10) Localized **subcutaneous** emphysema occasionally occurs at the tracheal entrance site within a few days of **catheter** placement and may be associated with tip migration. This is a report of a case of rapidly progressive and extensive **subcutaneous** emphysema occurring several weeks after **catheter** placement and not associated with **catheter** failure or migration.

CASE REPORT

A 73-year-old woman with previously diagnosed emphysema visited an acute care clinic approximately 1 month after placement of an **implanted intratracheal** oxygen **catheter** ((ITO.sub.2)C; Cook Critical Care; Bloomington, Ill) complaining of rapidly progressive swelling and intermittent sharp pain in the left anterior area of the **chest** . An area

approximately 20 cm in diameter visibly enlarged over a period of 30 to...

...area, or recent maneuvers likely to be associated with Valsalva or excess traction on the **catheter** . The patient had used this oxygen delivery **system** for the preceding 7 years. Two previous **catheters** had been removed because of persistent infection along the **catheter** tunnel. Her past medical history was significant for prior tobacco use (150 pack-years of...
...superior to the suprastemal notch. Crepitus was present over the left anterior segment of the **chest** adjacent to, the sternal border between the left clavicle and breast with extension laterally to...

...upper portion of the left arm but was not present in the neck. The oxygen **catheter** entered the **subcutaneous** tissue near the inferior costal margin and was palpable adjacent to the left sternal border. There was mild overlying tenderness but no erythema. The **chest** was hyperresonant to percussion, breath sounds were symmetrically diminished throughout the lung fields, and the...

...for a WBC count of 14.2 x (10.sup.3) cell/(micro)L. A **chest** radiograph demonstrated extensive **subcutaneous** emphysema. A limited CT scan (Fig 1) was obtained.

(Figure 1 ILLUSTRATION OMITTED)

Transtracheal oxygen was disconnected, and the patient was admitted for overnight observation with **supplemental** nasal **oxygen** . She was discharged the following morning with nearly complete resolution of her symptoms and reduced **subcutaneous** crepitus. Signs and symptoms suggestive of **subcutaneous** infection along the **catheter** subsequently developed, and she received a prolonged course of oral antibiotics for this problem. The patient resumed use of her **transtracheal** **catheter** approximately 1 week later. Within 2 weeks, complete resolution of **subcutaneous** emphysema was demonstrated radiographically.

DISCUSSION

Transtracheal oxygen delivery reduces oxygen use, enhances patient mobility and is cosmetically superior to nasal **cannula** . Although reports of potentially catastrophic mucus plug formation at the **catheter** tip have dampened enthusiasm for use in patients with copious mucus production, the devices are otherwise generally well-tolerated. This is a case of rapidly progressive and extensive **subcutaneous** emphysema associated with an intact and properly positioned **implanted** **intratracheal** oxygen **catheter** occurring approximately 5 weeks after placement. To date, the severity of **subcutaneous** emphysema experienced by the patient reported here and occurrence beyond the immediate postoperative period have...

...that the patient's paroxysm of coughing resulted in extravasation of tracheal gas at the **catheter** entrance wound with subsequent extension along the **catheter** tunnel and into the soft tissues of the **thorax** . Local scarring from the patient's two previous **catheters** may have limited extension of gas into the soft tissues of the neck. There was...

...the patient's underlying emphysematous lung disease contributed to this event. Transient migration of the **catheter** tip out of the trachea is unlikely to have occurred. A CT scan demonstrated appropriate **catheter** placement, and the **catheter** was anchored with ...to the anterior tracheal wall. Subsequent use of the device without complication suggests that the **catheter** did not fracture.

This case illustrates several important points in the management of **subcutaneous** emphysema in ambulatory patients with a **transtracheal** oxygen **catheter** . The tracheal **catheter** should be immediately disconnected from the oxygen supply and substituted with nasal prongs at a

slightly higher flow rate to meet the patient's oxygen requirements. Causes of **subcutaneous** emphysema unrelated to the **catheter** should be excluded promptly by taking a medical history, by performing a physical examination, and by carrying out appropriate radiographic studies. A limited CT scan to confirm proper **catheter** placement in the trachea is a logical next step. Migration of the **catheter** out of the trachea would require surgical intervention. Pharmacologic cough suppression and the early use of antibiotics would be prudent. A **catheter** tunnel infection may subsequently develop as in the reported patient and **subcutaneous** emphysema due to potentially life-threatening infection with gas-forming organisms needs to be considered.

Extensive **thoracic subcutaneous** emphysema and recurrent **catheter** tunnel infections are complications unique to **transtracheal** oxygen **catheters** with a long **subcutaneous** section. Similar complications do not occur with **transtracheal catheters** which exit the skin at the neck, similar to a conventional tracheostomy. Although initially quite alarming to this patient and possibly contributing to her subsequent **catheter** tunnel infection, the development of extensive **subcutaneous** emphysema was otherwise a benign and self-limited event. Despite the fact that the patient...

...possible that more aggressive cough suppression may have prevented this episode altogether.

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From the Division of Pulmonary and Critical Care Medicine (Drs. Blackmon...

...DESCRIPTORS: **Oxygen therapy** --...

... **Catheterization** --

19980300

24/3,K/54 (Item 43 from file: 149)
DIALOG(R)File 149:TGG Health&Wellness DB(SM)

01432652 SUPPLIER NUMBER: 14691123 (USE FORMAT 7 OR 9 FOR FULL TEXT)
The effects of transtracheal **gas delivery on central inspiratory neuromuscular drive.**
Scott, Graham C.; Hinson, James M.; Scott, Riley P.; Quigley, Patrick R.; Christopher, Kent L.; Metzler, Michael
Chest, v104, n4, p1199(4)
Oct,
1993
PUBLICATION FORMAT: Magazine/Journal ISSN: 0012-3692 LANGUAGE: English
RECORD TYPE: Fulltext TARGET AUDIENCE: Professional
WORD COUNT: 2289 LINE COUNT: 00234

The effects of transtracheal **gas delivery on central inspiratory neuromuscular drive.**

TEXT:

Previous studies have shown **transtracheal** delivery of low-flow oxygen (TTO) decreases inspired minute ventilation (VEINsp) and have postulated that...

...in WOB. We measured resting ventilatory parameters (RVP) and CIND by the mouth occlusion pressure **technique** (MOP) at different gas flow rates through the **catheter** in 21 subjects (13 men, 8 women; mean age, 60 [+ or -] 10.6 years) with severe **COPD** with a mature **intratracheal** oxygen **catheter** (ITOC). We also constructed a lung/ **chest wall** analog (LCA) to determine if flow through the **catheter** would alter pressure changes during inspiration. Inspiratory tidal volume (VTINsp) and minute ventilation (VEINsp) decreased proportionally to the gas flow rate through the **catheter** . However, with increasing flow through the **catheter** , P0.1 increased in the LCA, presumably due to the Bernoulli effect. The lack of ...

...is a decrease in WOB. This effect may be of benefit to patients with servere **COPD** .

Long-term **oxygen therapy** has been reported to reduce mortality in patients with severe chronic obstructive airways disease (**COPD**) and **hypoxemia** .[1,2] Use of a **transtracheal catheter** to deliver such **oxygen therapy** (TTO) has been advocated by some because of lower costs,[3] greater patient compliance,[4...

...decrease in the inspired minute ventilation (VEinsp) proportional to the flow of gas through the **catheter** . It was therefore postulated that the improvement in dyspnea and exercise tolerance seen in patients...
...ventilatory parameters (RVP), and if any such changes are associated with a change in CIND.

METHODS

Subjects

Twenty-one subjects (13 men, 8 women; mean age 60 [+ or -] 10.6 years) with severe **COPD** in whom an **intratracheal** oxygen **catheter** (ITOC) had been previously placed were studied. In three subjects, a modified Hickman **catheter** had been placed,[7] while in the remainder, a SCOOP **catheter** [10] was utilized. They were all studied while in clinically stable conditions. Written informed consent...

...15 min for equilibration, RVP and CIND, as assessed by the mouth occlusion pressure (MOP) **technique** , were measured as described

previously.[11] Each subject sat comfortably breathing via a mouthpiece through a two-way nonrebreathing **valve** (model 2700, deadspace 102.9 ml, Hans Rudolph, Kansas City, Mo) with an inspiratory occlusion pressure **valve** setup (series 9300, Hans Rudolph, Kansas City, Mo) attached to the inspiratory limb. The subject...

...model 3813, Hans Rudolph, Kansas City, Mo) was attached to the inspiratory side of the **valve** , and the flow signal from this together with the electronically integrated volume signal were recorded...
...fashion such that the subject could not anticipate closure, the inspiratory side of the nonrebreathing **valve** was completely occluded during expiration so that the next inspiration was occluded at functional residual...

...A minimum of six measurements was made in each subject.

The gas flow through the **catheter** was then adjusted and the above sequence of measurements repeated. The following flow rates were...

...made in each subject at each of the following flow rate: zero flow through the **catheter** , oxygen at 2, 4, and 6 L/min, and room air at 2, 4, and 6 L/min.

We were concerned that the flow of gas through the **catheter** would in and of itself affect the MOP measurement. We therefore repeated a second set of MOP measurements, but on this occasion, we momentarily occluded the ITOC **catheter** during the expiratory phase of the breath preceding the MOP measurement. As soon as the...

...Rudolph 8313, Hans-Rudolph, Kanas City, Mo) was attached to the expiratory limb of the **valve** , and the flow signal from this together with the electronically integrated volume signal were recorded...
...index of CIND.[12,13] Whether a flow of gas into the trachea changes the **system** and thereby invalidates the use of MOP has not been previously studied. To further address this issue, we constructed a mechanical analog of the lung, pleural space, and **chest wall** (LCA), modified from an original description by Chinet[14] (Fig 1). Briefly, a 15-mm internal diameter **tube** , 15 cm in length, is jointed to allow for **insertion** of variable resistors. The airway enters the test lung off-center for ...and maximum travel of 12 cm. The top and bottom plates of this cylinder are **sealed** Plexiglass, with the top plate allowing access for the airway, alveolar pressure measurement, and access...

...entrance into the cavity. The entire lung is encased within a 20-cm Lucite cylinder **chest wall** . This cylinder is 10 cm in length, is attached to the top plate, and has...

...outer diameter, 5-cm minimum length, with a 10-cm travel. The bottom of the **chest wall** is **sealed** with Plexiglass. The space between the lung and **chest wall** is **sealed** and tapped to allow measurement as the analog of pleural pressure.

The elastic recoil of...

...bottom plates of the lung. These may be changed to allow the elastance of the **system** to change. The **system** is steadied by a midsupport.

Elastic recoil of the **chest wall** is achieved by sets of counterbalancing springs that connect the **chest wall** plate with the top plate, and a separate set that connects the **chest wall** plate to the stand plate. These are also interchangeable and are of variable length to allow modification of the **chest wall** compliance.

We placed a **catheter** into this model at the point marked Paw Tap in Figure 1, to simulate the...

...pleural space to simulate "active" inspiration. Expiration was allowed to occur passively. Using the same **techniques** described above, we were then able to measure PO.1 during inspiration from FRC, in the airways during different gas flow rates through our ITOC **catheter** .

Statistical Analysis

Differences in each parameter of RVP and MOp, at different ITOC flows rates...

...or -] 2.8 percent. an oxygen flow of as little as 2L/min through the **catheter** , there was a significant increase to 95.9 [+ or -] 2.9 percent (p[less than...

...in PO. 1 or dP/dtmax was noted. During flow of room air through the **catheter** , the results were similar in that the only significant change noted was a fall in...

...satistical difference between the MOP measurements made during breif interruption of gas flow through the **catheter** with those obtained during uninterrupted flow (p[greater than]0.08).

[TABULAR DATA OMITTED]

Expiratory...

...and VE (VEexo - VEinsp) increased significantly with increasing flow rates of room air through the **catheter** ($p<0.003$) (Table 3). Similar results were found during oxygen flow.

Lidocaine

At each...

...after instillation of lidocaine through the ITOC.

Lung Model

P0.1 measurements obtained at different **catheter** flow rates in LCA are shown in Table 4. In this series, a pressure of...

...SaO.sub.2]

Table 4--P0.1 (cm [H.sub.2]O) Obtained at Different **Catheter** Flow Rates on the Lung/ **Chest Wall** Analog (LCA), Using a Pressure of - 10 cm [H.sub.2]O in the Pleural...were not able to directly show that CIND falls with increasing flow rates through the **catheter** . However, from our LCA, it would appear that MOP should in fact rise with increasing...

...to be the effect of the Bernoulli's principle. This law of fluid movement in **tubes** states that at any point in a **tube** through which liquid is flowing, the sum of all of the energies, (pressure, potential, and...

...describes this relationship: p + hdg + [1/2dv.sup.2] = k p = pressurem h = height of **system** , d = density, g = gravity, v = velocity, k = constant.

We postulate that the **insertion** of gas into a constant volume **system** caused d to increase (functional residual capacity did not change in the model by scalar...

...if g, h, and v remain the same. Since v was constant in the modeling **system** , p must decrease, and therefore be measured as a more megative (ie, larger) MOP.

From...

...flow. Longer studies with direct measurement of WOB appear to be warranted.

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19931000

24/3,K/58 (Item 47 from file: 149)
DIALOG(R)File 149:TGG Health&Wellness DB(SM)

01372866 SUPPLIER NUMBER: 12940182 (USE FORMAT 7 OR 9 FOR FULL TEXT)
Clinical experience and physiologic results with an implantable intratracheal **oxygen** catheter .
Jackson, Mark; King, Martin A.; Wells, Francis C.; Shneerson, John M.
Chest, v102, n5, p1413(6)
Nov,
1992
PUBLICATION FORMAT: Magazine/Journal ISSN: 0012-3692 LANGUAGE: English
RECORD TYPE: Fulltext TARGET AUDIENCE: Professional
WORD COUNT: 2920 LINE COUNT: 00300

Clinical experience and physiologic results with an implantable intratracheal **oxygen** catheter .

TEXT:

Ten patients with chronic lung disease received an **implanted** ITOC. Seven patients continue to use their **catheters** after a mean period of 14.75 months. Four **catheters** were removed, 2 at 1 month, 1 after 10 months and 1 after 13 months. One patient requested a second **catheter** . Three patients experienced mucus plug formation; this was transient in two patients, but led to removal of the 1catheter in the third. To determine the degree of oxygen-saving afforded by the ITOC, [SaO...

...at rest and during exercise for eight of the ten subjects using a double-blind **technique** . The calculated oxygen savings were around 40 percent both at rest and during exercise. The...

...to produce a useful saving of oxygen which is of benefit to patients using portable **systems** and those who require high oxygen flow rates.

Domiciliary oxygen is usually administered via a face mask or nasal **cannulae** , but **transtracheal** delivery has several advantages over these more traditional routes.[1] The major benefit is the...

...the flow rate required to maintain adequate oxygenation. This allows prolonged use of protable oxygen **systems** and adequate oxygenation of patients who require high flow rates. Studies of percutaneous **transtracheal catheters** have demonstrated reductions in the flow rate of around 50 percent. Other advantages include improved comfort and compliance with treatment. Conventional **transtracheal catheters** are, however, readily visible and require removal and reinsertion for cleaning. Some **transtracheal catheters** are liable to produce **subcutaneous** infection, **catheter** fracture and displacement,[2] which may make them unattractive to the patient and physician.

This article describes our clinical experience with a tunnelled **intratracheal catheter** which offers the benefits of **transtracheal** oxygen delivery with fewer drawbacks than the alternative designs. Our early experience with this **catheter** was encouraging[3] and has now been extended to ten patients.

MATERIALS AND **METHODS**

Subjects

The patients selected for the **procedure** all had chronic airflow obstruction or restrictive lung disease (Table 1). This was deemed severe enough to require **oxygen therapy** either continuously in order to improve their prognosis[4,5] or intermittently to improve exertional breathlessness. One subject could not safely receive nocturnal oxygen using nasal **cannulae** without unpredictable elevation of her arterial

[PCO.sub.2] because of changes of respiratory route and of **cannula** positioning during the night. The patients were all receiving maximal medical treatment for their respiratory disorders. This was unchanged for at least four weeks prior to **insertion** of the **catheter** and there had been no recent exacerbation of their illness. All patients had a careful...

...the exercise test. Patients 2 and 4 did not undergo any physiologic investigations because their **catheters** had been removed before the investigations were commenced.

The **Catheter - Insertion** and Postoperative Care

A 43-cm 11-F gauge Silicon **catheter** was used (Cook Critical Care ITOC **catheter**).[6] The proximal end of the **catheter** which lies within the trachea is short and is directed caudally (Fig. 1). The risk...

...A Dacron tissue ingrowth cuff is situated approximately two thirds of the way along the **catheter** to aid fixation in the **subcutaneous** tunnel. The **catheter** exit site is placed conveniently below the costal margin.

The **implantation procedures** all were performed with the subjects under local anesthesia and additional intravenous sedation. A perioperative antibiotic cover of benzylpenicillin and flucloxacillin was used. [TABULAR DATA OMITTED]

The **catheters** were flushed four times daily with 2 ml of sterile saline solution followed by 3...

...three weeks until the lower Dacron cuff was fixed in position. Oxygen administration through the **catheter** was delayed for an arbitrary period of five to seven days; early use of the **catheter** is thought to dry the **intratracheal** site and may delay healing and promote the formation of mucus plugs. An attempt was...

...violent coughing during the early postoperative period in order to minimize the risk of cervical **subcutaneous** emphysema. In all patients, the oxygen delivered through the **catheters** was not humidified. Direct traction on the **catheter** should be avoided at all times.

Physiologic Study **Method**

In both the rest and exercise studies, the subjects had nasal **cannulae** in position as well as tubing connected to their **intratracheal catheters** . Oxygen was delivered at varying flow rates in increments of 0.5 or 1 L...

...with an arbitrary additional rest period of 10 min.

RESULTS

Clinical Results and Complications

The **procedure** itself was tolerated well by all of our patients and no significant intraoperative complications occurred...

...patient experienced hemorrhage from the tracheostomy site and hemoptysis was either minimal or absent. The **catheter** was positioned successfully in the trachea in all of our patients, although in one, suturing...

...technical difficulty. The total operative time ranged from 30 to 50 min.

Small areas of **subcutaneous** emphysema around the tracheal site were noted in three patients in the immediate postoperative period...
...two days. Patients 2 and 9 developed increased dyspnea two to four weeks after the **procedure** as a result of the formation of a mucus plug around the **intratracheal** portion of the **catheter** . We performed bronchoscopy with the rigid bronchoscope on these patients as a rapid and reliably effective **method** for the removal of the mucus plugs. Patient 2 had been flushing his **catheter** inadequately and this problem did not recur following correction of the **technique** . In patient 9, two further

significant mucus plugs developed, causing respiratory embarrassment requiring further bronchoscopy...

...of tracheal stricture.

Patient 4, in whom suture of the tracheal disc was incomplete, developed **subcutaneous** emphysema and mild inflammation around the proximal site three weeks postoperatively. Radiography of the neck and fiberoptic bronchoscopy confirmed that the **catheter** had become displaced in the neck and it was removed through the **subcutaneous** tunnel. Patient 1 developed inflammation of the exit site due to protrusion of the cuff...

...being too low and its displacement through the exit hole by inadvertent traction on the **catheter** before fixation by tissue ingrowth had taken place. The inflammation settled for a period but...
...The ITOC was removed at that time, but at the patient's request, a second **catheter** was **inserted** four months later. The **catheters** of patients 2 and 7 fractured at the distal end adjacent to the oxygen adapter connection 16 and 13 months post- **insertion** , respectively. In both cases, they were repaired using a simple repair kit. None of the **catheters** fractured at any other site.

Patient 8 was admitted to the hospital with an infective exacerbation of emphysema three months post- **insertion** . She developed respiratory failure and needed endotracheal **intubation** and ventilation for five days. The endotracheal **tube** was shortened slightly for this purpose and the ITOC continued to function well. She experienced...

...patients continue to use their ITOCs. Patient 6 was able to return to work following **insertion** of the **catheter** . Patient 1 has since married. Of the four **catheters** removed, 2 were at 1 month, 1 at 10 months and 1 at 13 months. Of the 7 **catheters** in situ at present the mean duration of **catheter implantation** is 14.75 months (range, 4 to 22 months). The duration of **catheter implantation** is summarized in Figure 2.

Physiologic Results

Rest study: The [SaO.sub.2] values were...

...the lowest value when breathing air and the highest obtained with oxygen delivered through nasal **cannulae** was divided into quartiles. The interpolated flow rates that would achieve the quartile [SaO.sub...

...determine the flow rates required to achieve the maximum [SaO.sub.2] reached using nasal **cannulae** only (the fourth quartile point) the mean change at rest was 51 percent (95 percent...

...the differing prevention of desaturation during a standardized exercise test with the ITOC and nasal **cannulae** . The savings of oxygen flow rates to maintain the quartile [SaO.sub.2] values were...

...percent).

If the comparison was made at the maximum [SaO.sub.2] maintained using nasal **cannulae** (fourth quartile point), using the end exercise [SaO.sub.2] values, the mean flow rate...

...CI, 31.5 to 40.9 percent). These results are summarized in Figure 4.

DISCUSSION

Transtracheal delivery of oxygen has several reported advantages compared with use of nasal **cannulae** . It lessens the flow rate required to maintain adequate oxygenation.[7-9] The discomfort of nasal **cannulae** and face masks is removed and the device may improve patient compliance with long periods...

...because of decreased work of breathing resulting from a reduced inspired minute ventilation.[11]

Conventional **transtracheal** oxygen **catheters** have a number of drawbacks. Despite being less obtrusive than nasal **cannulae** or face masks, the visible **catheter** and **insertion** site are not cosmetically acceptable to all patients. The **catheters** are usually fixed with a necklace, but despite this, they may become displaced with a risk of loss of the **insertion** track.[12] Conventional **catheters** usually have a long **intratracheal** portion which is liable to fracture[2,13] or cephalad displacement and which is thought...

...14] and death if unrecognized.[15]

Two recent series clearly have documented the complications of **transtracheal oxygen therapy** using the SCOOP **system** . Adamo et al[16] reported a total of 120 complications in 21 patients during a...

...months). In that series many of the complications were not clinically significant but included two **catheter** misplacements into the mediastinum; ...cast. There were eight episodes of stomal or neck infection in six patients. While cleaning **catheters** , 8 patients experienced 11 episodes of inability to reinsert **catheters** into developed tracts and 7 patients experienced dislodgement of **catheters** on a total of 9 occasions--usually at night--requiring 5 repeat **procedures** . Two patients developed excessive external stomal granulation tissue. Hoffman et al[17] recently reported a series of 40 patients again using the SCOOP **system** . Ten (25 percent) of these patients experienced symptomatic mucus balls in the early phase. There were 18 episodes of **catheter** displacement with 6 lost tracts. Four patients had a probable bacterial cellulitis, one a cephalad displaced **catheter** and one a severed **catheter** . Five patients elected to discontinue its use.

The design of the **catheter** used in this study reduces some of these problems. It is cosmetically superior since it...

...skin in the subcostal region and is easily concealed in clothing. The fixation of the **catheter** is secure providing the disc is adequately sutured to the tracheal wall, and the effect...

...tracheal disc, leading to subsequent displacement. In a second patient, early inadvertent traction on the **catheter** displaced the lower Dacron cuff but not the tracheal portion of the **catheter** .

The neck site is closed and the long **subcutaneous** tunnel minimizes the risk of contamination of the neck wound. The **seal** provided by the fixation disc prevents infection of the neck from purulent secretions within the trachea. The design of the **catheter** with a short **intratracheal** portion is intended to reduce the risk of formation of mucus plugs. This problem has...

...our patients only if there has been a problem with compliance with flushing of the **catheter** following endotracheal **intubation** or as a result of an unusual granulation tissue reaction in the tracheal wall. All ...

...limiting the effectiveness of their cough may have predisposed them to mucus plug formation. The **catheter** is not removed for cleaning and therefore there is no risk of loss of the **insertion** track or of extratracheal placement. Two of the ITOCs fractured, but in both cases it was at the proximal end adjacent to the oxygen connection adapter and not in the **subcutaneous** or **intratracheal** portions.

The reduction of oxygen flow rate requirements using **transtracheal catheters** arises as a result of at least two mechanisms. First, wastage

around the nose and...

...greatly reduced.

Several authors have documented a range of oxygen savings at rest with percutaneous **transtracheal catheters** , but there are few accurate data regarding the reduction of flow rate on exercise when such reductions are most useful and no results of savings with a tunnelled **catheter** .

Heimlich and Carr[13] reported a 57 percent reduction at rest while maintaining therapeutic arterial blood gases. Using nasal **cannulae** , Leger et al[18] reported a reduction from a mean (SD) of 4.89 (1...

...percent reduction at rest with patients achieving similar exercise times using less oxygen through a **transtracheal catheter** . In a later study, Hoffman et al[17] reported an oxygen flow rate reduction of...

...standardized exercise test. This saving is very similar to the results previously obtained with percutaneous **catheters** with a long **intratracheal** section.

There are two main groups of patients who will benefit from the savings afforded...

...require high flow rates to achieve adequate oxygenation at rest will benefit. Using conventional nasal **cannulae** and an oxygen concentrator, high flow rates may be uncomfortable and poorly tolerated by the patient. Compliance with treatment is vital to achieve the reported benefits of long-term **oxygen therapy** . Additionally, in a few such patients the oxygen concentrator may not be able to deliver...

...required.

The second group is comprised of those who gain symptomatic benefit from portable oxygen **systems** . Their duration is increased in proportion to the oxygen conservation which, with the tunnelled **intratracheal catheter** , is approximately 40 percent.

Our experience with this group of patients confirms that the ITOC is an efficient and well-tolerated device for giving **supplemental oxygen** when it cannot be adequately provided by conventional means. An operative **procedure** is required for its **insertion** which is not needed for percutaneous **transtracheal catheters** , but it does not have the drawbacks of dislodgement and misplacement associated with these **catheters** which require removal, cleaning and replacement. It is, in addition, cosmetically superior. An ITOC, like other **transtracheal** devices, should only be used when there is a firm indication for this route of...order to comply with the daily care routine.

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DESCRIPTORS: **Catheterization --...**

... Intubation ;
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